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(71) Applicant: VENTRICA, INC. [US/US]; 976 Hamilton Avenue, Menlo Park, CA 94025 (US).

(72) Inventors: FOLEY, Mark, J.; 1151 Hobart Street, Menlo Park, CA 94304 (US). GITTINGS, Darin, C.; 520 South Bayview Avenue, Sunnyvale, CA 94086 (US).

(74) Agents: HESLIN, James, M. et al.; Townsend and Townsend and Crew LLP, Two Embarcadero Center, 8th floor, San Francisco, CA 94111-3834 (US).

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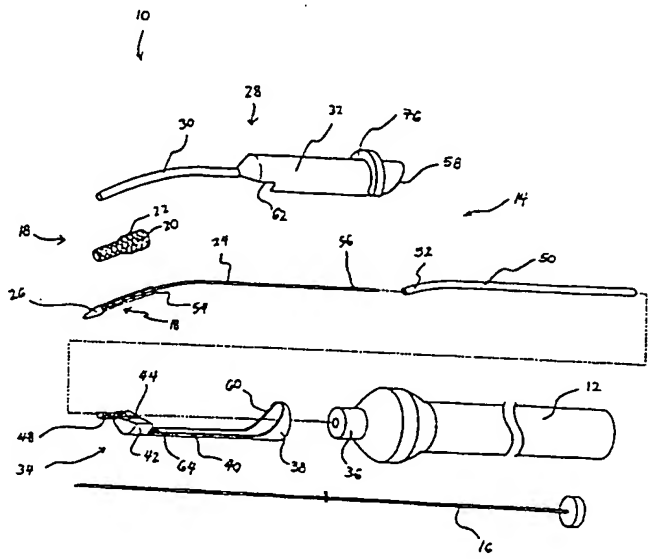

(57) Abstract

This invention is methods, and devices for forming a conduit (18) to place a target vessel in fluid communication with a source of blood, such as the aorta or a heart chamber. The conduit (18) may include a first conduit (118) including synthetic vascular graft material, such as PTFE, coupled to a second conduit (110) in the form of a hollow tissue structure, such as an autologous vessel. The first conduit (118) is secured to the target vessel. The second conduit (110) is secured to the first conduit (118), and is placed in fluid communication with a blood source.

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METHODS AND DEVICES FOR FORMING A CONDUIT BETWEEN A TARGET VESSEL AND A BLOOD SOURCE

CROSS-REFERENCES TO RELATED APPLICATIONS

This application is a continuation-in-part of the following U.S. patent applications: application serial no. 09/023,492, filed on February 13, 1998 and entitled "Methods and Devices Providing Transmyocardial Blood Flow to the Arterial Vascular System of the Heart," the entire subject matter of which is incorporated herein by reference; application serial no. 09/232,103, filed on January 15, 1999 and entitled "Methods and Devices for Forming Vascular Anastomoses," the entire subject matter of which is incorporated herein by reference; and application serial no. 09/232,062, filed on January 15, 1999 and entitled "Methods and Devices For Bypassing an Obstructed Target Vessel by Placing the Vessel in Communication with a Heart Chamber Containing Blood," the entire subject matter of which is incorporated herein by reference.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The invention relates to methods and devices for forming a conduit between a target vessel and a source of blood, and more particularly methods and devices for forming a conduit constructed at least in part of synthetic vascular graft material.

2. Description of the Background Art

Despite the considerable advances that have been realized in cardiology and cardiovascular surgery, heart disease remains the leading cause of death throughout much of the world. Coronary artery disease, or arteriosclerosis, is the single leading cause of death in the United States today. As a result, those in the cardiovascular field continue to search for new and improved treatments.

Coronary artery disease is currently treated by interventional procedures such as percutaneous transluminal coronary angioplasty (PTCA), atherectomy and placement of coronary stents, as well as surgical procedures including coronary artery bypass grafting (CABG). The goal of these procedures is to reestablish or improve blood flow through occluded (or partially occluded) coronary arteries, and is accomplished, for example, by enlarging the blood flow lumen of the artery or forming a bypass that allows

blood to circumvent the occlusion. What procedure(s) is used typically depends on the severity and location of the blockages. When successful, these procedures restore blood flow to myocardial tissue that had not been sufficiently perfused due to the occlusion.

CABG, the most common surgical procedure to treat coronary artery disease, uses a graft vessel to deliver oxygenated blood to a coronary artery downstream of an obstruction in the artery. For example, in a typical CABG procedure one end of a graft vessel is attached to the aorta (proximal anastomosis) and another end is attached to the coronary artery (distal anastomosis). The anastomoses are formed by suturing the graft vessel to the coronary artery and aorta, typically in an end-to-side manner.

Although suturing produces a strong anastomosis when done correctly, the procedure is highly technical and time consuming due to the small size of the vessels being joined. The procedure is particularly difficult when carried out minimally invasively because of limited access to the heart and coronary arteries. Further, forming a hand-sewn anastomosis on a beating heart is very challenging for a majority of surgeons. Most CABG procedures are performed on a stopped heart despite recognized drawbacks associated with cardiopulmonary bypass.

Another one of the difficulties associated with CABG procedures, and in particular multiple bypass procedures, is obtaining a sufficient number of conduits to bypass obstructions in several arteries. The conduits may comprise hollow tissue structures, e.g., the left and right internal mammary arteries, a saphenous vein or epigastroplegic artery. The conduits may also comprise synthetic vascular graft material, such as Dacron (polyester) or ePTFE (expanded polytetrafluoroethylene).

Synthetic vascular grafts having a diameter greater than about 5 mm have been shown to generally remain free of thrombus over an extended period of time. Grafts of this size are used to treat lesions in larger peripheral vessels including the distal abdominal aorta, the aortoiliac segment, and the renal arteries. The performance of smaller synthetic vascular grafts, such as those with a diameter of 5 mm or less, has been unsatisfactory as the grafts typically become occluded over a relatively short period of time. *See*, for example, Eric T. Choi and Allan D. Callow, *The Effect of Biomaterials on the Host*, in Implantation Biology, pp. 40-50, Ralph S. Greco Ed., (1994).

In addition to the cross-sectional size, length is another factor that may adversely affect the patency of synthetic vascular grafts as, for a given small diameter graft vessel, increasing the length will usually increase the likelihood of thrombosis. Other factors affecting patency include the particular material used for the conduit and its

characteristics, for example, the pore size or internodal distance of an ePTFE conduit. Patency may also be affected by joining the conduit to additional components, for example, an additional layer(s) of material, an internal and/or external support such as a stent, etc.

These limitations have effectively prevented the use of synthetic vascular grafts as conduits in CABG procedures. The coronary arteries that are treated during a CABG procedure typically have a diameter in the range of about 2-4 mm. In addition, the conduits must be long enough to extend from the blood source to a site on the artery distal to the lesion, for example, from the aorta to the distal left anterior descending artery (LAD). As such, the conduit size requirements associated with CABG procedures have limited the application of synthetic vascular graft materials in coronary procedures. Given the great number of CABG procedures performed every year, those in the art have attempted to develop conduits formed of synthetic vascular graft material that are suitable for use in bypassing obstructed coronary arteries.

As a result, graft vessels formed of tissue remain the most preferred and widely used conduits in CABG procedures. Using tissue graft vessels, though, has several drawbacks. For example, harvesting graft vessels from the patient's body is painful and traumatic and increases the length and recovery time associated with the procedure. Another drawback arises when treating patients who do not have a sufficient number of peripheral vessels that can be harvested and used as bypass conduits. The lack of conduits, for example, may be due to the patient already having undergone a CABG procedure(s) or having peripheral vascular disease. In either case the surgeon's options are limited due to the unavailability of tissue grafts for use as conduits.

Accordingly, there remains a need in the art for methods and devices for forming conduits between a target vessel, such as a coronary artery, and a source of blood, such as the aorta or a heart chamber, that may be used precisely and relatively quickly compared with current technology, and wherein the conduit is formed at least in part of synthetic vascular graft material.

SUMMARY OF THE INVENTION

According to one embodiment of the invention, a method is provided for forming a conduit to place a coronary artery in fluid communication with a source of blood. The method includes steps of providing a first conduit comprising synthetic vascular graft material, and securing the first conduit to a coronary artery to place the first

conduit in fluid communication with the coronary artery. A second conduit comprising a hollow tissue structure is adapted to be placed in communication with a source of blood and is secured to the first conduit. The second conduit is placed in fluid communication with a source of blood.

According to another embodiment, the invention provides a method for forming a conduit that is in fluid communication with a target vessel. This method includes steps of providing a tubular connector having a lumen, the tubular connector comprising a length of synthetic vascular graft material, and securing the tubular connector to a target vessel having a lumen. A graft vessel has a lumen and comprises a length of a hollow tissue structure. The graft vessel is secured to the tubular connector to form a conduit that places the lumens of the graft vessel and the target vessel in fluid communication.

According to yet another embodiment, the invention provides a method for increasing the flow of blood to a selected site in a patient's arterial vascular system. This method includes steps of inserting a first end of a conduit into a heart chamber containing blood, and inserting a second end of the conduit into the arterial vascular system at a selected site in the vascular system. The first and second ends of the conduit are connected together, and the conduit is maintained in an open position for blood flow through at least one of the diastolic and systolic phases of the heart cycle.

According to another embodiment, the invention provides a method for forming a conduit that is in fluid communication with a target vessel. The method includes steps of providing a tubular connector having a lumen and being movable between collapsed and expanded orientations, the tubular connector comprising a length of synthetic vascular graft material, and disposing a sheath over at least a portion of the tubular connector to hold the portion of the tubular connector in the collapsed orientation. The collapsed portion of the tubular member is placed at least partially into a lumen of a target vessel, and relative movement is imparted to the sheath and a sheath removal mechanism to remove the sheath and allow the collapsed portion of the tubular connector to expand against a wall of a target vessel.

Pursuant to another embodiment of the invention, a device is provided for being secured to a target vessel in fluid communication with the vessel lumen. The device includes a conduit adapted to be secured to a target vessel so as to be in fluid communication therewith, the conduit comprising synthetic vascular graft material. A vessel coupling is attached to the conduit in fluid communication with the conduit, and

the vessel coupling is movable to an expanded orientation to secure the vessel coupling and the conduit to a target vessel. The conduit may be secured to a graft vessel to establish a conduit that is in fluid communication with the target vessel.

According to another embodiment, the invention provides a system for forming a conduit that is in fluid communication with a target vessel having a lumen. The system includes a graft vessel comprising a hollow tissue structure, and a tubular connector secured to the graft vessel so as to be in fluid communication with the graft vessel. The tubular connector comprises synthetic vascular graft material, and a vessel coupling is attached to the tubular connector so as to be in fluid communication therewith. The vessel coupling is configured to be coupled to a target vessel so as to place the graft vessel in fluid communication with the target vessel.

According to another embodiment, the invention provides a device for being secured to a target vessel in fluid communication with a lumen of the target vessel. The device includes a tubular connector having a lumen and being movable between collapsed and expanded orientations, the tubular connector comprising a length of synthetic vascular graft material. A sheath is disposed over at least a portion of the tubular connector to hold the portion of the tubular connector in the collapsed orientation, and a sheath removal mechanism is disposed adjacent the sheath. The sheath and the sheath removal mechanism are relatively movable with respect to one another, and an actuator is coupled to at least one of the sheath and the sheath removal mechanism for imparting relative movement to the sheath and the sheath removal mechanism, which allows the portion of the tubular connector held collapsed by the sheath to expand against the wall of the target vessel wall.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention will be better understood from the following detailed description of preferred embodiments thereof, taken in conjunction with the accompanying drawing figures, wherein:

Fig. 1 is a perspective view of a device constructed according to a first embodiment of the invention for forming a conduit to place a target vessel in fluid communication with a source of blood;

Fig. 2 is an exploded perspective view of the device shown in Fig. 1;

Fig. 3 is an enlarged perspective view of a distal portion of the device shown in Fig. 1;

Fig. 4 is an exploded perspective view of the distal portion of the device shown in Fig. 3;

Fig. 5 is a fragmentary, longitudinal sectional view of the distal portion of the device shown in Figs. 3 and 4;

Figs. 6A-6B are schematic perspective views sequentially illustrating the removal of a sheath that forms part of the device shown in Fig. 1;

Fig. 7 is a schematic view of a patient prepared to undergo a cardiovascular surgical procedure, the patient's heart being exposed via a retractor positioned in a thoracotomy formed in the patient's chest;

Fig. 8 is a perspective view of the heart shown in Fig. 7 including an obstructed coronary artery, wherein the distal end of the device shown in Fig. 1 is positioned in the coronary artery;

Figs. 9A-9E are enlarged sectional views of a portion of the heart shown in Fig. 8 sequentially illustrating using the device shown in Fig. 1 to secure a conduit within the lumen of the coronary artery, wherein Fig. 9E shows the conduit after it has been placed in fluid communication with the artery;

Fig. 10 is a perspective view of the heart shown in Fig. 8 illustrating the conduit placed according to the steps shown in Figs. 9A-9D secured to the target vessel in fluid communication with the vessel lumen;

Fig. 10A is a perspective view showing the attachment of a conduit constructed according to another embodiment of the invention secured to a target vessel, wherein the conduit is configured to preserve native blood flow through the target vessel;

Fig. 11 is a perspective view of the exterior of the heart shown in Fig. 8 illustrating a first conduit secured to the artery and a second conduit adapted to be attached to the first conduit, wherein the second conduit is also adapted to be coupled to the aorta;

Fig. 12 is a perspective view of the heart shown in Fig. 11 illustrating a completed proximal anastomosis formed between the second conduit and the aorta;

Fig. 12A is a schematic perspective view of an instrument for coupling the second conduit to the first conduit, wherein an end of the second conduit is held in the instrument;

Fig. 13 is a perspective view of the heart shown in Fig. 12 after the first and second conduits have been coupled together to form a conduit that places the coronary artery in fluid communication with the aorta;

Fig. 14 is a perspective view of the exterior of the heart shown in Fig. 8 illustrating a first conduit secured to the artery;

Fig. 14A is a side elevation view of a second conduit adapted to be attached to the first conduit shown in Fig. 14, wherein the second conduit is also adapted to be placed in fluid communication with a heart chamber containing blood;

Fig. 15 is a perspective view of the heart shown in Fig. 14 illustrating the second conduit positioned in the myocardium in fluid communication with a heart chamber containing blood;

Fig. 15A is a schematic perspective view of an instrument for coupling the second conduit to the first conduit, wherein an end of the second conduit is held in the instrument;

Fig. 16 is a perspective view of the heart shown in Fig. 15 after the first and second conduits have been coupled together to form a conduit that places the coronary artery in fluid communication with a heart chamber containing blood; and

Fig. 16A is a sectional view taken through the myocardium illustrating the second conduit positioned in the myocardium so as to be in fluid communication with the heart chamber.

DESCRIPTION OF THE SPECIFIC EMBODIMENTS

Referring to Figs. 1-5, a device constructed according to one preferred embodiment of the invention is indicated generally by the reference numeral 10 and is used to place a target vessel in fluid communication with a source of blood. The device 10 comprises a handle 12, a shaft assembly 14 and an optional incising component 16 (Fig. 2). The incising component 16 is used to penetrate tissue in order to introduce the device into a target vessel. While a separate incising component is shown in the Figures, the incising component could instead be formed as an integral part of the device. Further, it will be appreciated that the device 10 may be used without an incising assembly for piercing tissue, for example, by placing the shaft assembly 14 through a surgical incision in the vessel wall.

If used with an incising element, such as component 16, the shaft assembly of the device may be provided with a bore that receives the incising element and allows it to be extended and retracted with respect to the device. One benefit of providing a bore through the shaft assembly of the device is that the conduit is protected from contact with any element located in the bore. Thus, an incising element, guide wire, guide catheter,

etc., may be used without risk of damage to the conduit, the bore allowing the device to be passed over a guide wire or catheter that has been introduced into the lumen of a vessel. Moreover, the bore may be configured to act as a flashback lumen to indicate to the user that the device has entered a lumen containing blood, for example, a coronary artery or heart chamber.

The shaft assembly 14 may be relatively flexible to permit the shaft assembly to bend during the procedure, or it may be substantially rigid. The degree of flexibility imparted to the shaft assembly 14 of the device 10, as well as the dimensions of the device 10, will vary depending on the application and user preference. The device 10 could be formed with a shaft assembly 14 that is curved, malleable so as to be bendable to a selected configuration, or articulated with a movable portion that may be controlled or steered, for example, by known mechanisms used to steer catheters or guide wires.

As an example of a range of possible constructions, the device 10 may be relatively short with the shaft assembly 14 substantially rigid for use in an open-chest procedure. Alternatively, the device 10 may be relatively long with the shaft assembly 14 rigid or flexible for use in a minimally invasive procedure. As yet another alternative, the device may be even longer (with the shaft assembly 14 flexible or rigid) for use in an endoscopic procedure, wherein the actuators for controlling the device components are located adjacent the proximal end of the device to allow remote deployment of the vessel coupling. An example of a device configured for use in a minimally invasive procedure is disclosed in co-pending, commonly owned application no. 09/304,140, filed on May 3, 1999, and entitled "Methods and Devices for Placing a Conduit in Fluid Communication With a Target Vessel," the entire subject matter of which is incorporated herein by reference.

In the application illustrated in the Figures, the invention is used to establish a conduit between a target vessel and a source of blood. The conduit may comprise one member, or it may comprise multiple conduits coupled to form a conduit between the target vessel and the blood source. The conduit is preferably formed, either partially or completely, of synthetic vascular graft material. It should thus be appreciated that reference to a first or a second conduit in connection with describing one preferred embodiment is not intended to limit the scope or application of the invention.

The conduit preferably comprises a tubular connector that is at least partially constructed of synthetic vascular graft material and is configured to be placed in fluid communication with the target vessel. The tubular connector preferably includes a

vessel coupling adapted to be secured to the target vessel. One preferred vessel coupling is constructed so that it may be secured to the target vessel by a substantially suture-free attachment, which means that the attachment is not a conventional hand-sewn anastomosis created by suturing the members together. As such, although some suture may be used, in this preferred embodiment the vessel coupling (or conduit without a vessel coupling) is attached to the target vessel by means other than a typical, hand-sewn sutured connection. The invention, however, may be practiced using a conduit without a vessel coupling, for example, by using suture to secure the conduit to the target vessel.

Further, the vessel coupling used to attach the conduit to the target vessel is preferably expandable so that the coupling may be collapsed for introduction into the target vessel and then expanded into contact with the vessel wall. Nonetheless, it will be understood that the invention may be carried out by using a vessel coupling that comprises a non-expandable structure; for example, the vessel wall could be dilated to receive a tubular element and then allowed to move against the element to hold it in place in the vessel.

The illustrated device 10 is adapted to place a conduit that is coupled to another conduit to establish a conduit. As noted above, the conduit may comprise any number of sections or portions. The conduit 18 includes a vessel coupling in the form of a stent 20 and a liner 22 formed of synthetic vascular graft material coupled to the stent 20. As an example, the stent 20 may be a self-expanding nitinol stent 20 and the liner or layer 22 may be a tubular length of teflon (PTFE) or expanded teflon (ePTFE). The stent may be laser cut from a tube of material so as to include a plurality of struts that permit the stent to move between collapsed and expanded orientations. Other stent constructions may be used instead; for example, the stent could be wire-formed or could comprise a flat sheet of material that is unrolled to an expanded orientation. The liner 22 is secured to the stent 20 by any suitable means, for example, suture (not shown) passing through the liner wall and the wall of the stent. Other suitable means for securing the two components include biologically compatible adhesives, ultrasonic welding, clips or fasteners, weaving the liner through the stent elements, tying the liner to the stent elements, etc.

As an example, the stent may be cut or formed by subjecting a tube of suitable material to any of various procedures such as laser cutting, EDM (electrical discharge machining), photochemical etching, etc. The stent/tube material is preferably nitinol, but may be titanium, tantalum, etc. It may be desirable to further process or finish

the cut stent to remove burrs or surface irregularities, for example, by acid etching, electropolishing, or abrasive blasting. Next, the frame sections that engage the wall of the target vessel are shape-set to their expanded orientation. This may be done by placing the frame sections in that orientation and applying sufficient heat to produce a structure that will assume the desired configuration above a certain temperature, e.g., 5 ° below body temperature. The stent may then be placed in its collapsed orientation by cooling (e.g., with liquid nitrogen), coupled to a liner and loaded onto a delivery device, and then deployed in a target vessel.

As shown in Fig. 2, the proximal and distal ends of the stent 20 and the liner 22 are preferably aligned so that the two components are generally coextensive. Rather than being coextensive, though, the stent 20 and liner 22 could partially overlap each other a desired extent so that either has a portion that is uncovered. For example, the distal portion of the stent 20 could extend beyond the distal end of the liner 22 so as to be exposed for engagement with the target vessel. The extent that the stent 20 and liner 22 overlap may be different from that shown, and the stent may be disposed within the liner, as shown, or it may be disposed outside the liner. Finally, while the illustrated conduit 18 includes only the stent 20 and liner 22, an additional layer(s) of material, such as a layer of ePTFE, silicone, or another stent, may be included along with the stent 20 and the liner 22.

The invention may be carried out by establishing a conduit that comprises any suitable synthetic vascular graft material, either alone or in combination with another component or material, synthetic or tissue. The conduit may comprise a relatively short length of a suitable synthetic vascular graft material, for example, a woven or knitted material such as Dacron (polyester), PTFE or ePTFE. However, as used herein the phrase synthetic vascular graft material encompasses any material suitable for use as a substitute for natural blood vessels. As an example, the conduit may comprise ePTFE having an inner diameter within the range of from about 1 mm to about 5 mm, and more preferably about 2 mm to about 4 mm, a wall thickness of about 0.2 mm, and an internodal distance or pore size in the range of from about 20 μs to about 100 μs.

The conduit of the invention preferably comprises a relatively short length of synthetic vascular graft material in order to avoid thrombosis problems that arise with longer vessels formed of the same materials (as discussed above). If the procedure being carried out requires a longer length conduit to extend between the target vessel and blood source, the invention may provide a second conduit that is coupled to the first conduit.

The second conduit is preferably a tissue vessel in order to avoid thrombosis problems associated with longer vessels formed of synthetic graft materials, although the conduit could comprise only synthetic vascular graft material. It should also be appreciated that the diameter, length and material of construction of the conduit may vary.

As shown in Figs. 1 and 2, the conduit 18 is preferably somewhat bell-shaped when in its expanded orientation. This shape may be provided to facilitate coupling the conduit 18 to a second conduit, for example, by docking an end of the second conduit into the larger end of the bell-shaped first conduit. In use, the liner 22 is preferably secured to the stent 20 prior to collapsing the stent from the expanded orientation to a smaller profile (shown in phantom in Fig. 2), in which the conduit 18 is not bell-shaped. It will be recognized that alternative configurations, with or without a larger diameter opening for coupling the conduit, may be used if desired.

The conduit 18 is supported by a support member 24 which may be in the form of a shaft sized and configured to mount the stent 20 and liner 22. The support shaft 24 is preferably provided with a nose cone dilator 26 having one or more tapered surfaces for introducing the device into the lumen of a target vessel, the dilator preferably being formed of a soft, floppy atraumatic material. Alternative or additional means for dilating the target vessel may be used as well.

The illustrated device 10 utilizes a self-expanding stent 20; thus, the device is not provided with an expansion mechanism for deploying the stent. If desired, though, the device may include such a mechanism, for example, an inflatable balloon, in order to use the device with a stent that is forced to an expanded orientation. This embodiment of the invention may be practiced using the teachings disclosed in application serial no. 09/232,102, filed on January 15, 1999, and entitled "Methods and Devices for Forming Vascular Anastomoses," the entire subject matter of which has been incorporated herein by reference. Additionally, the device could be provided with a separate inflation lumen for inflating the balloon to expand the stent, or the design in the aforementioned application may be used with suitable seals such as O-rings or the like.

The shaft assembly 14 of the illustrated embodiment also includes a retention mechanism, indicated generally at reference numeral 28, for retaining the self-expanding stent 20 in its collapsed orientation during introduction into the lumen of the target vessel. The retention mechanism 28 comprises a sheath 30 carried by a sheath hub 32 which is adapted to be removably supported by the device 10. The device 10 is provided with an actuator for imparting relative motion to the sheath 30 and the conduit

18 to deploy the conduit in the target vessel. In the illustrated embodiment, the sheath hub 32 acts as the actuator; however, it will be appreciated that alternative actuators may be used to impart the relative motion, e.g., actuators using cables, lever assemblies, etc. The sheath 30 is preferably formed of a thin-walled, flexible material, e.g., polyolefin, nylon, polyimide, PEEK, Hytrel, etc.

The device 10 also includes a positioning mechanism, indicated generally by the reference numeral 34, for engaging the retention mechanism 28 and the conduit 18. The positioning mechanism 34 serves to maintain proper orientation of the conduit 18 and the retention mechanism 28, with respect to each other and with respect to the remaining components of the device.

As shown in Figs. 1 and 2, the distal end of the handle 12 has a boss 36 which is used to mount the positioning mechanism 34. In particular, the positioning mechanism 34 has a proximal end portion 38 with an opening sized and configured to receive the boss 36. The mechanism 34 is preferably fixed to the handle 12 by any suitable means, for example, adhesives, brazing, welding, fasteners, etc. The positioning mechanism 34 includes a base 40 which extends away from the handle 12 and leads to a distal end portion 42 which supports the conduit 18 and conduit support member 24. In the illustrated embodiment, the positioning mechanism 34 includes a mechanism for removing the sheath 30 from the device 10. The distal end portion 42 has a groove 44 sized to receive the shaft of the support member 24, a slot 46 that accommodates the sheath removal mechanism, and a positioning member 48 that engages the conduit 18 and the sheath 30 to maintain the components in position during use. See Figs. 2-4.

The conduit 18 is mounted on the support member 24 and retained in its collapsed orientation (Fig. 2) by the sheath 30. The sheath 30 preferably covers the entire length of the conduit 18, although it could overlie only a portion of the conduit. For example, the sheath could be constructed, positioned and actuated in a manner the same as or similar to that disclosed in the aforementioned co-pending, commonly owned application no. 09/304,140, filed on May 3, 1999, the entire subject matter of which application has been incorporated herein by reference.

The illustrated embodiment also includes a sleeve 50 for maintaining the conduit in position on the support member 24 during use. The sleeve 50 is sized and shaped so that it can be slid over the support member 24 until the distal end 52 of the sleeve abuts the proximal end 54 of the conduit 18. The opposite end of the sleeve 50 abuts (or is fixed to) the boss 36 of the handle 12. The distal end of the conduit 18 abuts

the nose cone dilator 26 so that the conduit 18 is held in position on the support member 24 between the nose cone dilator 26 and the sleeve 50.

The support member 24, with the conduit 18, sheath 30, hub 32 and sleeve 50 mounted thereon, is passed through the opening in the proximal end 38 of the positioning mechanism 34. The proximal portion 56 of the support member 24 is inserted into the bore in the handle 12 and then fixed in position. The shaft assembly 14 thus extends distally away from the handle 12, and the proximal end of the support member 24 may be either movably or immovably secured to the handle.

The sheath hub 32 is provided with a surface 58 configured to mate with a complementarily formed surface 60 on the positioning mechanism 34, which allows the components to nest together and present a smooth outer profile, as shown in Fig. 1. Similarly, the sheath hub 32 has a cutout 62 that mates with a step 64 formed on the positioning mechanism 34. When assembled as shown in Fig. 1, the positioning member 48 preferably extends between the outer surface of the conduit 18 (and in particular the outer surface of liner 22) and the inner surface of the sheath 30.

As viewed best in Figs. 6A-6B, the lower portion of the sheath 30 rests directly beneath the positioning member 48, which preferably has an arcuate shape that substantially conforms to the contour of the conduit 18 and the sheath 30. The positioning member 48 serves to shield the conduit 18 (and in particular the liner 22) from the mechanism for removing the sheath, which is disposed in the slot 46 formed in the distal end portion 42 of the positioning mechanism 34.

Referring to Figs. 3-5, the sheath removal mechanism is indicated generally by reference numeral 66 in Fig. 4 and comprises a cutting blade 68 with a cutting edge 70 for splitting the sheath 30. The cutting blade 68 is fixed to the positioning member 48 and extends into the slot 46 in the distal end portion 42 of the positioning mechanism 34. In the illustrated embodiment, the cutting blade 68 and positioning member 48 are separate from the distal end portion 42. The cutting blade 68 has an aperture 72 which is aligned with an aperture 74 in the distal end portion 42 to receive a set screw (not shown) that fixes the components in position. Fig. 5 shows the cutting blade 68 located in the slot 46 with cutting edge 70 facing the distal end of the device. The sheath hub 32 is preferably provided with a portion, such as the flange 76 shown in Figs. 1 and 2, that may be grasped to move the sheath 30 with respect to the sheath removal mechanism 66.

Figs. 6A-6B show schematically the sheath 30 being removed from the conduit 18. It should be noted that the sheath 30 may be integral with the hub 32 or it may be a separate element attached thereto. The sheath hub 32, support member 24 and sleeve 50 are omitted from Figs. 6A-6B for sake of clarity; however, in use the flange 76 would be grasped to move the hub 32 in a proximal direction to split the sheath 30. Fig. 6A shows the positioning member 48 located between the sheath 30 and conduit 18 such that the proximal end of the sheath is located within the slot 46 so as to rest against the cutting edge 70 of the blade 68. The lower wall of the proximal end of the sheath 30 may have a slit that is placed over the cutting blade 68.

The sheath 30 is moved in the direction of the arrow shown in Fig. 6B which moves the cutting edge 70 through the sheath to form a split 78 that runs along the length of the sheath. As the sheath 30 is moved proximally against the cutting blade 68, the sleeve 50 retains the conduit 18 in position and the positioning member 48 ensures that the conduit 18 does not contact the cutting blade 68. As shown in Fig. 6B, the sheath 30 is split so that it can be removed from the device. This allows the conduit 18, and in particular the stent 20 which forms the vessel coupling in the illustrated embodiment, to expand into contact with the target vessel wall in order to secure the conduit to the target vessel.

The sheath removal mechanism 66 may be modified or omitted depending on the specific construction of the device. As an example, it should be understood that the cutting blade 68 (or alternative sheath removal mechanism) and positioning member 48, rather than being attached to the device 10, may instead be integrally formed with the device 10. Further, the sheath 30 may have an alternative construction, for example, the sheath may be a peel-away type that is pulled apart and removed, or a non-splitting member that undergoes relative motion with respect to the conduit 18 in order to expose the conduit. It will be appreciated that if the conduit utilizes a vessel coupling that does not have to be expanded to secure the conduit to the target vessel, then the sheath may be omitted altogether. A sheath may nonetheless be desirable in order to protect the tissue of the target vessel during introduction of the device.

It should be appreciated that a device constructed according to the invention could include removable or detachable components, or could be constructed as a one-piece instrument with no separable components. The device may be formed as a disposable instrument, a reusable instrument capable of being sterilized, or a combination of disposable and reusable components.

Referring now to Figs. 7-9E, an exemplary method for placing a conduit in fluid communication with a target vessel according to one embodiment of the invention will be described. Fig. 7 schematically depicts a patient who has been prepared to undergo a cardiovascular surgical procedure. A thoracotomy T is formed in the patient's chest by making an incision between two ribs to provide access to the thoracic cavity. A retractor R may be used to spread the ribs and increase access to the heart H and great vessels. The retractor preferably raises one side of the incision with respect to the other side to increase the working space around the heart. Any suitable retractor may be used, for example, one of the commercially available rib retractors currently used in minimally invasive cardiac surgery. As shown, the retractor R provides considerable access to the heart H and great vessels including the aorta A. The left side of the heart as well as the left coronary artery LCA is easily accessible via the thoracotomy T.

Fig. 8 shows the heart H in isolation along with a device 10 constructed as described above. Fig. 8 is an anterior view of the heart H showing the left ventricle LV, right atrium RA, aorta A, pulmonary trunk PT and pulmonary veins PV. The left coronary artery, including the circumflex branch and the left anterior descending branch LAD, is visible in this view, as is the right coronary artery RCA. The coronary arteries run along the heart wall and deliver oxygenated blood to the myocardial tissue. An occlusion or blockage O partially (or completely) obstructs the lumen of the LAD, which results in inadequate or no blood flow to the heart wall tissue fed by the portion of the LAD that is downstream of the occlusion O. It will be appreciated that the particular target vessel and source of blood shown in the Figures are exemplary only as there will be numerous applications for the methods and devices disclosed herein.

As shown in Fig. 8, the distal end of the device 10, and in particular the tip of the incising component 16 and the nose cone dilator 26, is passed through the wall of the LAD. The device 10 may be manipulated with respect to the heart H in order to obtain the most advantageous angle of entry into the coronary artery. The illustrated device 10 has a curved shaft assembly 14 configured to allow easier cannulation of the target vessel. The particular manner in which the device 10 is oriented will of course depend on the specific application, including the particular vessel being treated and whether the procedure is being carried out, for example, in an open-chest manner via a median sternotomy or a minimally invasive manner via one or more smaller surgical openings (such as the thoracotomy T in Fig. 7). In any event, the device 10 is held and

manipulated to achieve an optimal position for passing the distal end smoothly into the lumen of the LAD.

Figs. 9A-9D are sectional views corresponding to Fig. 8 but showing only the portion of the LAD and the heart wall M adjacent the point of entry of the device 10. As can be seen in Fig. 9A, the sharpened tip of the incising component 16 is exposed inside the lumen of the LAD. The incising component 16 is retracted once the distal end of the device 10 has been passed through the wall of the LAD. Once this has been done, the device 10 is introduced further into the LAD, preferably by angling the device as shown in Fig. 9B. The device 10 is moved into the lumen of the LAD a sufficient amount to place the conduit 18 at a predetermined location within the LAD.

The device 10 may be provided with means for indexing the position of the device in order to control the position of the conduit 18 with respect to the target vessel. Suitable means for indexing the position of the device 10 include markings (not shown) placed along the shaft assembly 14, for example, the sheath 30, that may be read with respect to the wall of the target vessel to determine the position of the conduit 18 with respect to the target vessel. Other means include one or more stops carried by the shaft assembly 14 for engaging or contacting tissue to control the position of the conduit 18 in the target vessel. Additionally, the sheath 30 may be transparent to allow the user to view the conduit 18 and visually confirm its position in the target vessel.

Fig. 9C shows the sheath 30 partially split as a result of moving the sheath against the cutting blade 68. As described above, the flange 76 (not shown in Fig. 9C) is grasped and moved in a proximal direction. This pulls the sheath 30 against the edge 70 of cutting blade 68, which forms a split 78 in the sheath. The split 78 allows the sheath 30 to be removed from the device, and in particular the conduit 18 which is either partially or completely covered by the sheath. As the remaining length of the sheath 30 is split and removed the formerly covered portion of the conduit 18 is exposed. The conduit 18 moves to its expanded orientation once the stent 20 is no longer restrained by the sheath 30.

Once the conduit 18 has been uncovered and assumes its expanded orientation, the size of the conduit is sufficient to allow the nose cone dilator 26 to be passed through the conduit (as can be seen from Fig. 9C). Alternatively, the nose cone dilator could be collapsible in order to remove it through the conduit. After removing the sheath 30, the remainder of the device 10, i.e., the support member 24, nose cone dilator 26, positioning member 48, and sleeve 50 are removed from the conduit 18. The

resulting configuration is shown in Fig. 9D, wherein the expanded conduit 18 engages the wall of the LAD and provides a secure attachment.

In the illustrated embodiment, the reduced diameter distal portion 80 of the conduit 18 is disposed substantially entirely within the lumen of the LAD. The larger diameter proximal portion 82 of the conduit 18 is disposed entirely outside the lumen of the LAD. The larger diameter portion 82 of the conduit 18, which is bell-shaped in the illustrated embodiment but could be shaped differently if desired, is presented for attachment to a second conduit (not shown in Fig. 9D). It is preferred to have a portion of the conduit 18 extend through the opening in the wall of the target vessel to enhance the seal formed at the junction.

Fig. 10 shows the completed conduit as viewed from the exterior of the heart H. The conduit 18 extends through the wall of the LAD and is adapted to be coupled to another conduit placed in communication with a source of blood. It should be recognized that position and orientation of the conduit with respect to the target vessel may be varied from the exemplary configuration illustrated in Figs. 9D and 10.

Depending on the construction of the device, securing the conduit to the target vessel may partially or completely obstruct the lumen of the target vessel. For example, as shown best in Fig. 9D, the lumen of the LAD may be occluded by the conduit 18, and in particular by the liner 22, once the conduit has expanded to its final position. As a result, native blood flow through the target vessel may be hindered or prevented from moving distally past the attachment site between the conduit and the vessel. In the case of a coronary artery, the conduit 18 could limit or block native blood flow through the artery, e.g., blood from the aorta flowing through the artery. Many patients undergoing a CABG procedure will have some native proximal blood flow in one or more obstructed arteries. It therefore would be desirable to place a conduit in fluid communication with the target vessel in a manner that preserves such native blood flow in the target vessel.

Accordingly, another embodiment of the invention provides methods and devices for attaching a conduit comprising synthetic vascular graft material to a target vessel while preserving native blood flow through the target vessel. That is, blood flowing through the target vessel prior to placing the conduit is free to flow past the site of the attachment. One way of achieving this is by forming the conduit 18 with a portion comprising uncovered stent that is placed in the target vessel to allow flow past the junction. Another way to preserve flow is by forming an opening in the portion of the

conduit that is placed in the target vessel, for example, an opening through the stent 20 and the liner 22.

Fig. 10A shows a conduit constructed according to this embodiment of the invention for preserving native flow in the target vessel. The conduit is designated by the reference numeral 90 and has a similar construction as the conduit 18 described above with respect to the previous embodiments. The conduit 90 comprises a stent 92 and a liner 94, each of which may be constructed as described above regarding the stent 20 and liner 22. The stent 92 of the conduit 90, however, has a different construction in that the distal portion is configured to engage the target vessel without blocking blood flow through the target vessel.

In particular, the stent 92 has a frame structure 96 including one or more sets of frame elements 98 that secure that conduit 90 to the target vessel yet allow blood flow through the vessel, as indicated by the arrows in Fig. 10A. The conduit 90 may be collapsed (in whole or in part) for introduction into the target vessel and then expanded to engage the vessel wall. The embodiments of the invention that preserve native blood flow through the vessel may be practiced using the methods and devices disclosed in the aforementioned application serial no. 09/232,103, filed on January 15, 1999, as well as the aforementioned co-pending, commonly owned application no. 09/304,140, filed on May 3, 1999, the entire subject matter of which applications has been incorporated herein by reference.

The illustrated embodiment of the invention that preserves native blood flow through the target vessel has a construction that does not cover a major portion of the inner or posterior wall of the vessel. As can be seen from Fig. 10A, the frame structure 96 contacts the inner wall of the vessel but leaves the majority of the vessel wall uncovered. This allows blood flowing through the target vessel to feed septal perforators (not shown but extending downward as viewed in Fig. 10A), which feed blood to the myocardial tissue. This feature thus prevents the myocardial tissue perfused by the septal perforators from becoming ischemic due to the conduit located in the target vessel. It should be appreciated that while it is preferred to leave the majority of the vessel wall unexposed to perfuse as many septal perforators as possible, the invention may be practiced with a conduit that covers more or less of the vessel wall than that shown.

An exemplary method for establishing a conduit according to the invention to place a target vessel in fluid communication with a source of blood will be described in connection with Figs. 11-13. Fig. 11 illustrates a heart wherein a first conduit 18 has

been secured to the LAD, for example, by the method described above with respect to Figs. 8-9D. The first conduit 18 is adapted to be coupled to a second conduit to establish the conduit that communicates the artery and blood source. Figs. 11-13 depict the invention being used to carry out a CABG procedure. The first conduit 18, shown attached to the LAD downstream of the obstruction O in Figs. 11-13, is adapted to be secured to a second conduit 100 that is placed in fluid communication with the source of blood. However, if desired the first conduit 18 may have a length sufficient to allow it to be placed in fluid communication with the LAD and the aorta. The second conduit 100 preferably comprises a hollow tissue structure, and most preferably an autologous tissue structure, for example, a saphenous vein harvested from the patient. The second conduit 100 could alternatively comprise synthetic vascular graft material, such as PTFE or ePTFE.

The proximal end 102 of the second conduit 100 may be prepared as is known in the art for anastomosis to a source of oxygenated blood, which in this embodiment is the aorta A. An aortotomy AO is formed in the wall of the aorta, for example, by making an incision and using an aortic punch (not shown). The distal end 104 of the second conduit 100 is preferably joined to a vessel coupling adapted to be secured to the first conduit 18. The vessel coupling may be in the form of a stent 106 that is collapsed for introduction into the first conduit 18 and then expanded to secure the two conduits together.

Fig. 12 shows the proximal end 102 of the second conduit 100 sutured to the aorta in conventional fashion to form a proximal anastomosis. It should be appreciated that the proximal end 102 of the conduit 100 could be secured to the aorta (or other blood source) by alternative means, such as a vessel coupling carried by the end 102, which vessel coupling may be in the form of a stent.

Next, the conduit 100 is clamped off to block blood flow from the aorta A (not shown). The stent 106 carried by the distal end 104 of the second conduit 100 may be collapsed by any suitable mechanism for introduction into the first conduit 18. As an example, an instrument 108 may be in the form of forceps with a pair of jaws that are used to collapse a portion of or the entire stent 106 so that it may be positioned in the first conduit 18 (Fig. 12A). If necessary, a second instrument may be used to gradually expand the stent 106 in the first conduit 18 in order to allow the instrument 108 to be removed. The illustrated second conduit 100 is secured to the stent 106 so that a portion of the stent 106 is exposed. The portion of the stent 106 that is exposed may be more or

less than that shown; for example, the stent 106 may be entirely covered by the distal end 104 of the second conduit 100. In any case, the distal end 104 of the second conduit 100 is coupled to the first conduit 18 via a secure, fluid-tight connection.

Fig. 13 shows the completed conduit that is formed by the conduits 18, 100 in order to communicate the LAD with the aorta. In the illustrated procedure the proximal end 102 of the conduit 100 is first coupled to the blood source and then coupled to the conduit 18; this may be desirable in order to expel air from the interior of the conduit. The specific manner in which the procedure is carried out may be varied, for example, by first coupling the distal end 104 of the conduit 100 to the conduit 18 and then to the blood source. Also, as an example, the length of the conduit extending between the aorta and the coronary vessel may be in the range of from about 5 cm to about 8 cm (including the portion of the conduit disposed in the vessel).

The procedure according to this embodiment of the invention provides several benefits over conventional CABG procedures. For example, utilizing a conduit that comprises synthetic vascular graft material allows the device to be supplied with the conduit loaded on the device. Also, the relatively short length of synthetic vascular graft material that is exposed to blood minimizes the risk of or prevents thrombosis in the conduit. Further, the invention enables the user to secure a conduit to the target vessel without (or substantially without) using suture.

One aspect of the invention thus obviates the need to create a hand-sewn sutured distal anastomosis between the conduit and the target vessel, which is a highly technical component of CABG procedures, particularly if carried out minimally invasively. As cardiovascular treatments have continued to become more and more minimally invasive with reduced access to the heart, suturing extremely small blood vessels together has become more difficult and time-consuming. Thus, a significant advantage of the invention is that the distal anastomosis may be formed relatively quickly and easily during a minimally invasive, beating heart procedure. Finally, if an autologous tissue structure is used as a conduit, then the user need only harvest the tissue graft (as is conventionally done) and secure same to a vessel coupling, such as the stent 106, that is adapted to be secured to the first conduit.

Turning now to Figs. 14-16A, another exemplary method for placing a conduit constructed according to the invention in fluid communication with a target vessel and a source of blood will be described. In the procedure exemplified in Figs. 14-16A, though, the target vessel (LAD) is placed in fluid communication with a heart

chamber containing blood, rather than the aorta. Thus, the aorta A in Figs. 11-13 does not have an aortotomy; otherwise, the heart and the first conduit 18 are depicted the same in the respective groups of Figures.

Fig. 14A illustrates in detail a second conduit 110 which is adapted to be coupled to the first conduit 18 and placed in fluid communication with a heart chamber containing blood. In the Figures, the heart chamber is the left ventricle; however, it will be understood that another heart chamber could be used if desired. The second conduit 110 comprises a graft vessel 112 preferably formed of synthetic vascular graft material, for example, the same material used to form the first conduit 18. The graft vessel 112, though, could be formed of tissue or a different synthetic vascular graft material. The distal (or blood outlet) end 116 of the second conduit 110 is preferably provided with a vessel coupling that may be in the form of a stent 118 constructed in the same manner as the stent 106 described above with respect to the embodiment of Figs. 11-13. The proximal (or blood inlet) end 120 of the second conduit 110 is preferably provided with a fitting 114 configured to be positioned in the myocardium such that the vessel 112 is in fluid communication with the heart chamber.

The fitting 114 is preferably a hollow cylinder formed of any suitable biocompatible material, such as stainless steel, titanium, tantalum, polymers, etc. The graft vessel 112, which may be a length of ePTFE, is positioned in the fitting 114 with the proximal end 120 everted over the end of the fitting. The proximal end 120 is secured to the fitting 114 by suitable means, such as the sutures shown in Fig. 14A. The fitting 114 may be provided with recesses 122 (or alternative structure) adapted to receive or support the suture. The attachment of the vessel 112 to the fitting 114 may also be achieved using silicone, biologically compatible adhesives, clamps rings, etc. An internal component, such as a stent, may also be provided to force the graft vessel 112 against the fitting 114 in order to ensure the vessel wall does not kink or collapse within the fitting.

The fitting 114 also is preferably provided with a mechanism to assist in maintaining the proximal end 120 of the conduit 110 patent once positioned in the myocardium, for example, by preventing tissue or other matter moving over and blocking flow into the proximal end. For instance, the end of the conduit that is placed in the ventricle will be located near tissue such as the chordae tendineae, papillary muscle or other myocardial tissue, thereby creating the risk of such tissue blocking the flow of blood into the conduit.

One preferred component for preventing blockage of the conduit is shown in Fig. 14A and comprises a structure comprising a plurality of struts defining open areas through which blood may flow. As shown, a plurality of struts 124 are secured to the fitting 114, each strut 124 having one end 126 fixed to the fitting 114 and another end 128 positioned adjacent the proximal end 120 of the conduit 110. The struts 124 extend away from the fitting 114 and then converge to a location at which the ends 128 are joined. The resulting configuration forms a frame or cage around the end of the conduit 110 that will be placed in fluid communication with the heart chamber. In addition to preventing blockage by the aforementioned tissue structures, the component will prevent or minimize tissue being forced into the fitting 92 during placement of the fitting in the myocardium.

While the illustrated mechanism includes four curved struts 124, fewer or more struts may be used, and the struts may be straight, curved, or otherwise shaped, and may be rigid or flexible. Further, it will be readily appreciated that alternative mechanisms for preventing blockage of the end of the conduit that communicates with the heart chamber (or other blood source) may be used in lieu of that illustrated in Fig. 14A. For example, rather than a plurality of individual struts, the mechanism could comprise a grid or mesh that allows blood to flow into the conduit 110.

The dimensions of the fitting 114 may vary depending on the application. As an example, the fitting 114 may be formed from 8 gauge thin wall 304 stainless steel hypo tube stock and be approximately 23 mm long. The struts 124 may be formed from 304 full hard stainless steel wire and be approximately 18 mm long with an outer diameter of approximately 0.375 mm. If constructed as in the illustrated embodiment, the length of the portion of each strut 124 extending beyond the proximal end 120 of the graft vessel 112 may be approximately 8 mm.

Fig. 15 shows the conduit 110 after it has been positioned in the myocardium M such that the proximal end 120 is in fluid communication with the left ventricle LV. This may be achieved by making a stab incision partially or entirely through the myocardium M and then placing the fitting 114 in the tissue at a location that permits blood to flow from the ventricle into the conduit 110. The fitting 114 may be designed to rest entirely within the myocardium, which would allow the user to visually confirm proper placement of the conduit 110. Alternatively, the fitting 114 (or another part of the conduit 110) may be provided with markings or other means for indicating the position of the end of the conduit that is placed in the left ventricle LV.

The fitting 114 is preferably sized and configured to securely engage the tissue of the myocardium without requiring suture or other fastening means. To that end, the fitting 114 may be provided with a roughened surface or a layer(s) of material that enhances fixation in the tissue. Of course, the fitting 114 could be positively secured to the tissue by suture or other fasteners if desired. Further, the fitting 114, or another portion of the conduit 110 that engages the tissue of the myocardium, may be used to deliver various drugs to the tissue. For example, the fitting 114 itself or a sleeve of material provided on the fitting may be impregnated with a pharmaceutical composition, such as angiogenic growth factor, heparin, etc. The sleeve (not shown) could comprise a metal or a polymer, for example, ePTFE, PTFE, Dacron, etc.

From the position shown in Fig. 15, the second conduit 110 is clamped off (not shown) and its distal end 116 is coupled to the open end of the first conduit 18 that has been secured to the LAD. In the illustrated embodiment, the distal end 116 is provided with a stent 118, and for that reason may be coupled to the conduit 18 in the same manner described above with respect to Figs. 11-13. As shown in Fig. 15A, the instrument 108 with movable jaws may be used to collapse a portion of or the entire stent 118 so that it may be positioned in the conduit 18. As explained above, if necessary, a second instrument may be used to gradually expand the stent 118 in the first conduit 18 in order to allow the instrument 108 to be removed. The illustrated second conduit 110 has a portion of the stent 118 exposed. Also as explained above, the exposed portion of the stent 118 may be greater or less than that shown. If desired, the stent 118 may be entirely covered by the distal end of the conduit 110. In any case, the distal end of the conduit 110 is preferably coupled to the conduit 18 to provide a secure, fluid-tight connection.

Fig. 16 shows the completed conduit that is formed by the conduits 18, 110 in order to communicate the target vessel (the LAD) with a heart chamber (the left ventricle LV). In the illustrated procedure the proximal end 120 of the conduit 110 is first coupled to the blood source, and the distal end 116 is then coupled to the conduit 18, as discussed above with respect to the previous embodiment. It should be noted, though, that the distal end 116 of the conduit 100 could be coupled to the conduit 18 first, with the proximal end 120 then secured to the myocardium. In either case, the result is a fluid tight, preferably suture-free attachment between the conduit 110 and the conduit 18 and between the conduit 110 and the blood source. As an example, the length of the conduit extending between the heart chamber and the coronary vessel may be in the range of from

about 3.5 cm to about 5 cm (including the portion of the conduit disposed in the myocardium).

Fig. 16A is a sectional view of the proximal end 120 of the conduit 110 positioned in the myocardium M. The fitting 114 is generally coextensive with the myocardium M; however, the length of the fitting 114 could instead be less or greater than the thickness of the myocardium. Similarly, the struts 124 could be positioned partially within the myocardium M, as shown, or completely outside the myocardium within the heart chamber LV. Also, as noted above, the conduit 110 could be provided with an internal support such as a stent (not shown).

Those in the art will recognize many possible variations of the invention as described and illustrated herein. The Figures show a coronary artery being placed in fluid communication with a source of blood selected from the aorta and the left ventricle. It should be understood that the target vessel may be any hollow body structure having a lumen, such as any coronary or peripheral vessel, and any blood-containing hollow body structure, such as heart chamber, any of the great vessels, or another vessel.

Also, while an expandable vessel coupling is illustrated, a rigid or non-expandable vessel coupling may be used to establish the conduit. The coupling may comprise a rigid tube that is sized and configured to be secured to the target vessel. For example, the conduit could be oversized with respect to the target vessel and the vessel dilated up to receive the conduit. The target vessel would then close back down around the conduit to securely hold the components together without using suture. Further, the conduit (including one or more of the conduits) could have means for preventing kinking of the conduit, for example, by providing the conduit with a pre-formed shape and/or by disposing a strain relief-type element, such as a spring wire, on one or more areas of the conduit, as disclosed in the aforementioned co-pending, commonly owned application no. 09/304,140, filed on May 3, 1999, the entire subject matter of which has been incorporated herein by reference.

The conduit also could be provided with a valve or other means for controlling or regulating blood flow. A valve could be provided in one or more of the conduits and could take the form, for example, of any of the valves disclosed in co-pending, commonly owned application serial no. 09/023,492, filed on February 13, 1998, and entitled "Methods and Devices Providing Transmyocardial Blood Flow to the Arterial Vascular System of the Heart," the entire subject matter of which has been incorporated herein by reference.

Similarly, it will be appreciated that a conduit or vessel coupling configured to preserve native blood flow in a target vessel may be constructed differently than that shown. For example, the portion of the vessel coupling that is disposed in the target vessel could take the form of a conventional coronary stent joined to the portion of the coupling disposed in the graft vessel. Further, the portion of the vessel coupling that permits native flow through the target vessel could control or meter the flow. Other variations may be used as well.

It will be appreciated that the features of the various preferred embodiments described herein may be used together or separately, while the illustrated methods and devices may be modified or combined in whole or in part. As an example, the attachment formed between the conduit and the target vessel may be suture-free while allowing or blocking native flow through the target vessel; alternatively, the attachment may be formed to allow native flow through the target vessel but be created using to some extent conventional suturing techniques.

Further, it will be understood that the embodiments may be used in various types of procedures, for example, the surgical approach depicted in the Figures, an open surgical procedure including a median sternotomy, or a minimally invasive procedure utilizing one or more relatively small access openings or ports. Endoscopes or thoracoscopes may be used for visualization if the procedure is truly minimally invasive. Similarly, the different embodiments may be used in beating heart procedures, stopped-heart procedures utilizing cardiopulmonary bypass (CPB), or procedures during which the heart is intermittently stopped and started. Finally, any suitable delivery device, instrument or catheter may be used in conjunction with the invention.

It also will be recognized that the invention is not limited to the illustrated applications. For example, the invention may be used to establish arteriovenous shunts, perform a femoral-femoral bypass, treat peripheral arterial disease in the distal abdominal aorta including the infrarenal aorta and aortoiliac segment, aortofemoral, or carotid, and to treat disease in the iliac and renal arteries.

The preferred embodiments of the invention are described above in detail for the purpose of setting forth a complete disclosure and for sake of explanation and clarity. It will be readily understood that the scope of the invention defined by the appended claims will encompass numerous changes and modifications.

WHAT IS CLAIMED IS:

1. A method for forming a conduit to place a coronary artery in fluid communication with a source of blood, the method comprising steps of:

a) providing a first conduit comprising synthetic vascular graft material;

b) securing the first conduit to a coronary artery to place the first conduit in fluid communication with the coronary artery;

c) providing a second conduit comprising a hollow tissue structure, wherein the second conduit is adapted to be placed in fluid communication with a source of blood;

d) securing the second conduit to the first conduit so that the second conduit is in fluid communication with the first conduit; and

e) placing the second conduit in fluid communication with a source of blood.

2. The method of claim 1, wherein the second conduit is secured to a source of oxygenated blood.

3. The method of claim 2, wherein the source of oxygenated blood is the aorta, and the conduit is secured to the aorta by a hand-sewn sutured anastomosis.

4. The method of claim 1, further comprising securing the first conduit to the coronary artery so as to allow blood flow in the coronary artery to move past the attachment site between the first conduit and the coronary artery.

5. The method of claim 1, further comprising securing the first conduit to a coronary artery without using suture to form a substantially suture-free attachment that places the first conduit in fluid communication with the coronary artery.

6. The method of claim 5, wherein first and second expandable vessel couplings are respectively used to secure the first conduit to the coronary artery and the second conduit to the first conduit without using suture.

7. The method of claim 1, wherein the first conduit comprises ePTFE and is secured to the coronary artery by a self-expanding stent.

8. A method for forming a conduit that is in fluid communication with a target vessel, the method comprising steps of:

a) providing a tubular connector having a lumen, the tubular connector comprising a length of synthetic vascular graft material;

b) securing the tubular connector to a target vessel having a lumen;

c) providing a graft vessel having a lumen, the graft vessel comprising a hollow structure; and

d) securing the graft vessel to the tubular connector to form a conduit that places the lumens of the graft vessel and the target vessel in fluid communication.

9. The method of claim 8, wherein the tubular connector comprises a length of ePTFE and the graft vessel comprises a length of hollow tissue structure.

10. The method of claim 8, wherein the tubular connector is secured to a first vessel coupling that is secured to the target vessel.

11. The method of claim 10, wherein the first vessel coupling is expandable, and step (b) is carried out by placing the first vessel coupling at least partially within the lumen of the target vessel and expanding the first vessel coupling against the wall of the target vessel.

12. The method of claim 11, wherein the first vessel coupling comprises a self-expanding stent and step (b) is carried out by removing a sheath to allow the stent to expand within the lumen of the target vessel.

13. The method of claim 10, wherein the first vessel coupling is configured to allow blood flow in the lumen of the target vessel to move past the attachment site between the tubular connector and the target vessel.

14. The method of claim 8, wherein the graft vessel comprises a length of an autologous tissue structure.

15. The method of claim 8, wherein the graft vessel is secured to a second vessel coupling that is secured to the tubular connector.

16. The method of claim 15, wherein the second vessel coupling is expandable, and step (d) is carried out by placing the second vessel coupling at least partially within the lumen of the tubular connector and expanding the second vessel coupling against the wall of the tubular connector.

17. The method of claim 6, wherein the second vessel coupling comprises a stent and step (d) is carried out by expanding the stent within the lumen of the tubular connector.

18. The method of claim 8, wherein step (d) is carried out by securing the graft vessel to the tubular connector by suture.

19. The method of claim 8, wherein step (d) is carried out by securing the graft vessel to the tubular connector by a clamp that at least partially surrounds the graft vessel and the tubular connector.

20. The method of claim 8, wherein at least one of steps (b) and (c) is carried out without using suture.

21. The method of claim 8, further comprising placing the graft vessel in fluid communication with a source of oxygenated blood selected from the group consisting of the left atrium, right atrium, left ventricle and right ventricle.

22. A method for increasing the flow of blood to a selected site in a patient's arterial vascular system, the method comprising the steps of:

a) inserting a first end of a conduit into a heart chamber containing blood;

b) inserting a second end of the conduit into the arterial vascular system at a selected site in the vascular system;

c) connecting the first and second ends of the conduit together; and

d) maintaining the conduit in an open position for blood flow through at least one of the diastolic and systolic phases of the heart cycle.

23. The method of claim 22, wherein the first end of the conduit is carried by a first conduit comprising tissue and the second end of the conduit is carried by a second conduit comprising synthetic vascular graft material, and wherein step (c) is

carried out by securing the first and second conduits together in fluid communication with each other.

24. The method of claim 22, wherein the heart chamber is the left ventricle, and further comprising regulating the blood flow in the conduit to minimize blood flow from the arterial vascular system to the left ventricle during the systolic phase of the heart cycle.

25. The method of claim 22, wherein the conduit remains open during both the systolic and diastolic phases of the heart cycle.

26. The method of claim 22, wherein the second end of the conduit receives blood from more than one source.

27. A method for forming a conduit that is in fluid communication with a target vessel, the method comprising steps of:

a) providing a tubular connector having a lumen and being movable between collapsed and expanded orientations, the tubular connector comprising a length of synthetic vascular graft material;

b) disposing a sheath over at least a portion of the tubular connector to hold the portion of the tubular connector in the collapsed orientation;

c) placing the collapsed portion of the tubular member at least partially into a lumen of a target vessel; and

d) imparting relative movement to the sheath and a sheath removal mechanism to remove the sheath and allow the collapsed portion of the tubular connector to expand against a wall of a target vessel.

28. The method of claim 27, wherein step (d) is performed by moving the sheath against a cutting element to sever the sheath and expose the tubular connector.

29. A device for being secured to a target vessel in fluid communication with a lumen of the vessel, the device comprising:

a conduit adapted to be secured to a target vessel so as to be in fluid communication with a lumen of the target vessel, wherein the conduit comprises synthetic vascular graft material; and

a vessel coupling attached to the conduit so as to be in fluid communication with the conduit, wherein the vessel coupling is movable to an expanded orientation to secure the vessel coupling and the conduit to the target vessel;

wherein the conduit may be secured to a target vessel and a graft vessel secured to the conduit to establish a conduit that is in fluid communication with the target vessel.

30. The device of claim 29, wherein the conduit comprises a tubular connector formed at least in part of a synthetic vascular graft material selected from the group consisting of PTFE, ePTFE and Dacron.

31. The device of claim 30, further comprising a support shaft removably supporting the tubular connector and the vessel coupling, wherein the support shaft includes a sheath overlying at least the vessel coupling.

32. The device of claim 31, wherein the vessel coupling is expandable and the sheath is retracted prior to expanding the vessel coupling.

33. The device of claim 32, further comprising an expansion mechanism for forcing the vessel coupling to the expanded orientation to secure the vessel coupling to the target vessel without using suture.

34. The device of claim 29, wherein the vessel coupling is sized and configured to be attached to a target vessel while allowing native blood flow in the target vessel to move past the attachment site between the vessel coupling and the target vessel.

35. A system for forming a conduit that is in fluid communication with a target vessel having a lumen, the system comprising:

a graft vessel comprising a hollow tissue structure;

a tubular connector secured to the graft vessel so as to be in fluid communication with the graft vessel, wherein the tubular connector comprises synthetic vascular graft material; and

a vessel coupling attached to the tubular connector so as to be in fluid communication with the tubular connector, wherein the vessel coupling is configured to be coupled to a target vessel so as to place the graft vessel in fluid communication with the target vessel.

36. The system of claim 35, wherein the tubular connector comprises ePTFE and the graft vessel comprises an autologous tissue structure.

37. The system of claim 35, wherein the vessel coupling is sized and configured to be attached to a target vessel while allowing native blood flow in the target vessel to move past the attachment site between the vessel coupling and the target vessel.

38. A device for being secured to a target vessel in fluid communication with a lumen of the target vessel, the device comprising:

a tubular connector having a lumen and being movable between collapsed and expanded orientations, wherein the tubular connector comprises a length of synthetic vascular graft material;

a sheath disposed over at least a portion of the tubular connector to hold the portion of the tubular connector in the collapsed orientation;

a sheath removal mechanism disposed adjacent the sheath, wherein the sheath and the sheath removal mechanism are relatively movable with respect to one another;

an actuator coupled to at least one of the sheath and the sheath removal mechanism for imparting relative movement to the sheath and the sheath removal mechanism to allow the portion of the tubular connector held collapsed by the sheath to expand against a wall of a target vessel.

39. The device of claim 38, wherein the sheath comprises a thin wall polymer sleeve and the sheath removal mechanism comprises a blade.

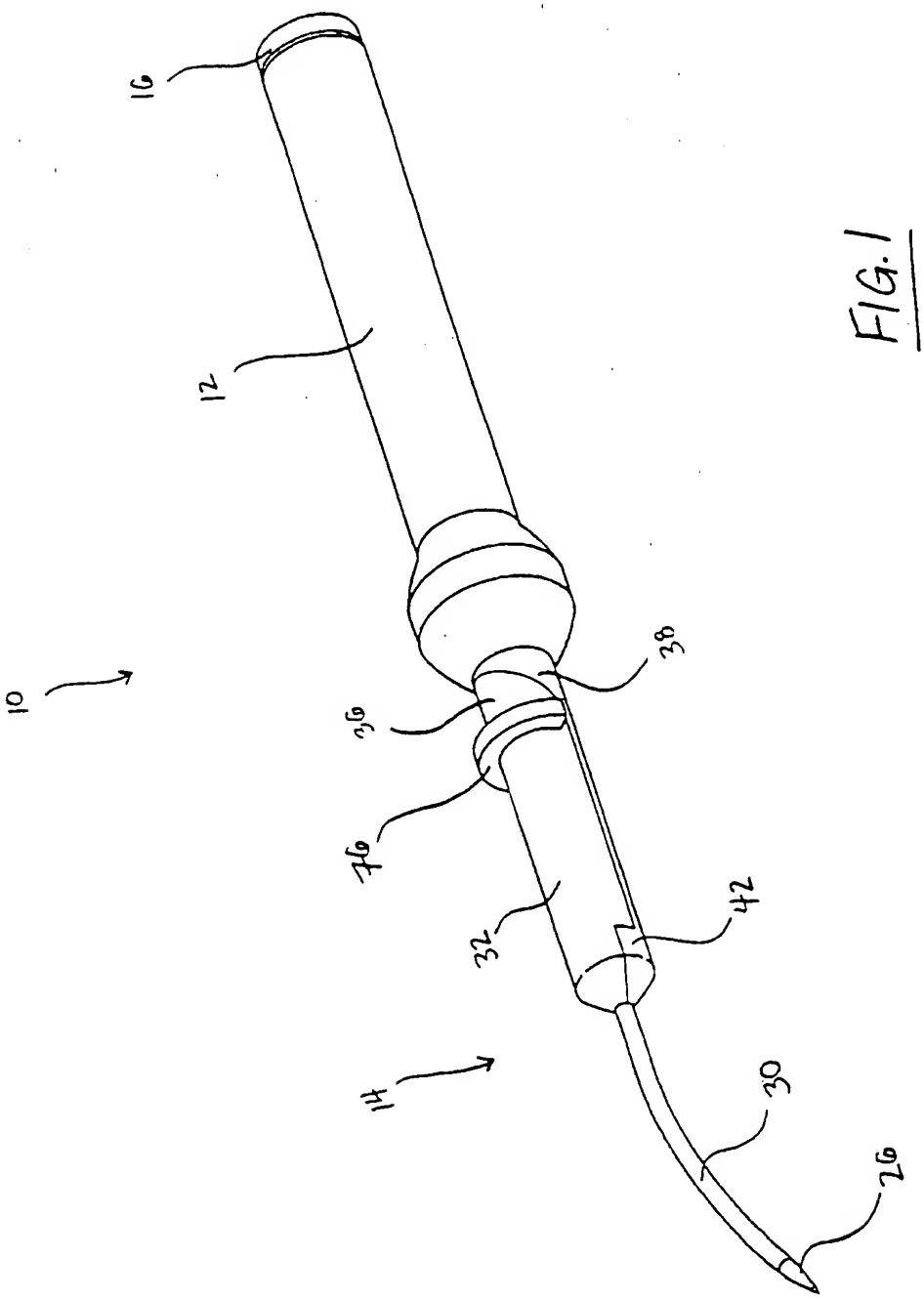

FIG. 1

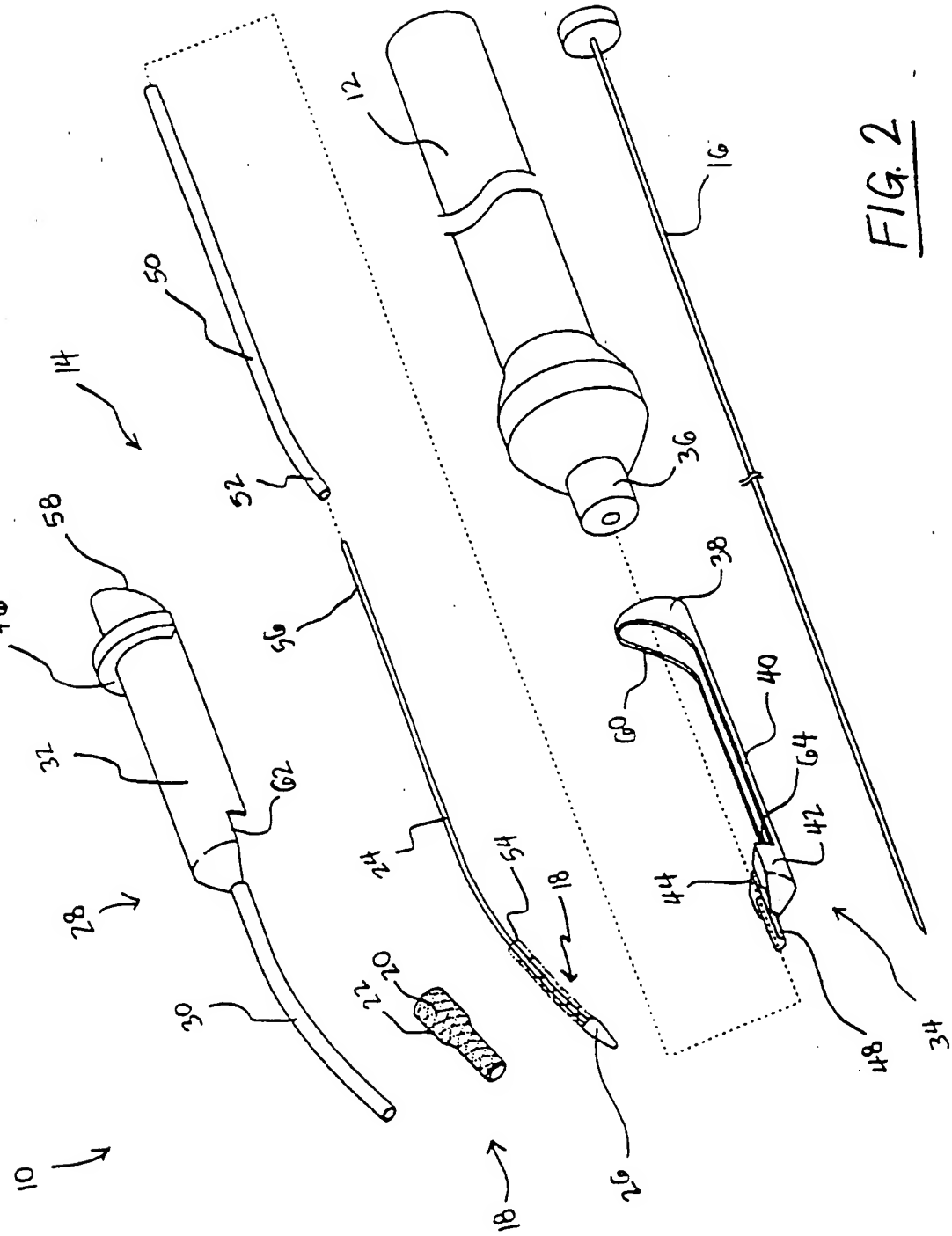
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FIG. 2

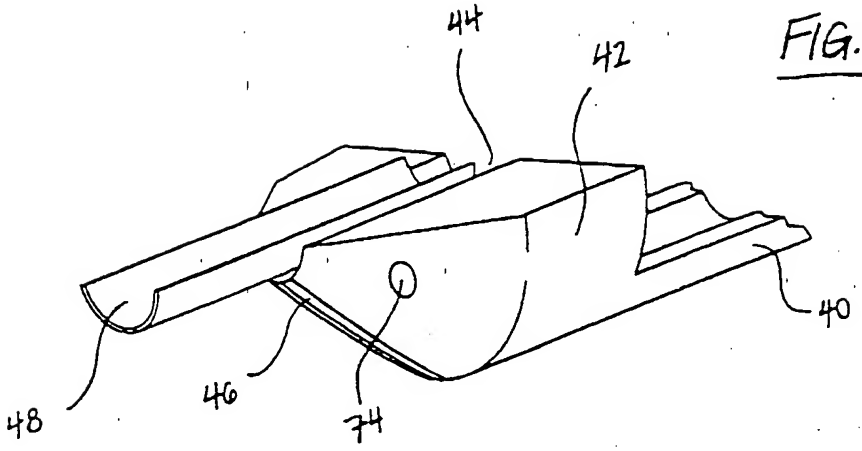


FIG. 3

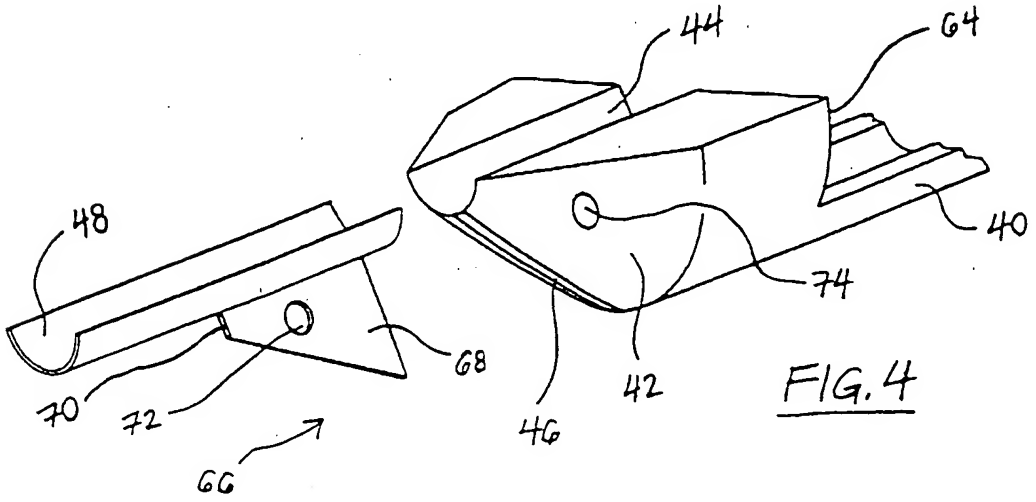


FIG. 4

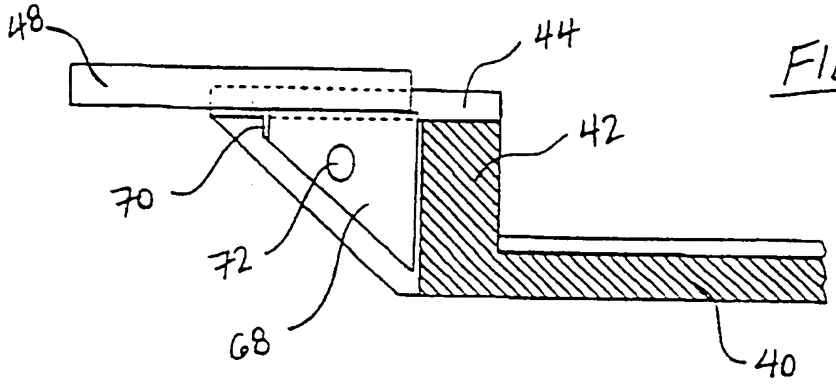


FIG. 5

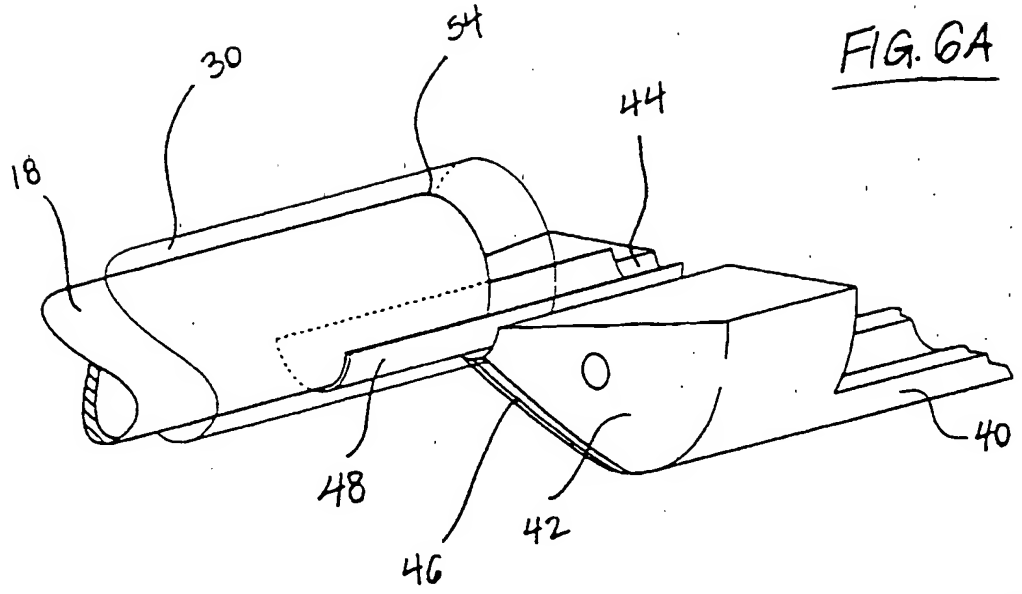
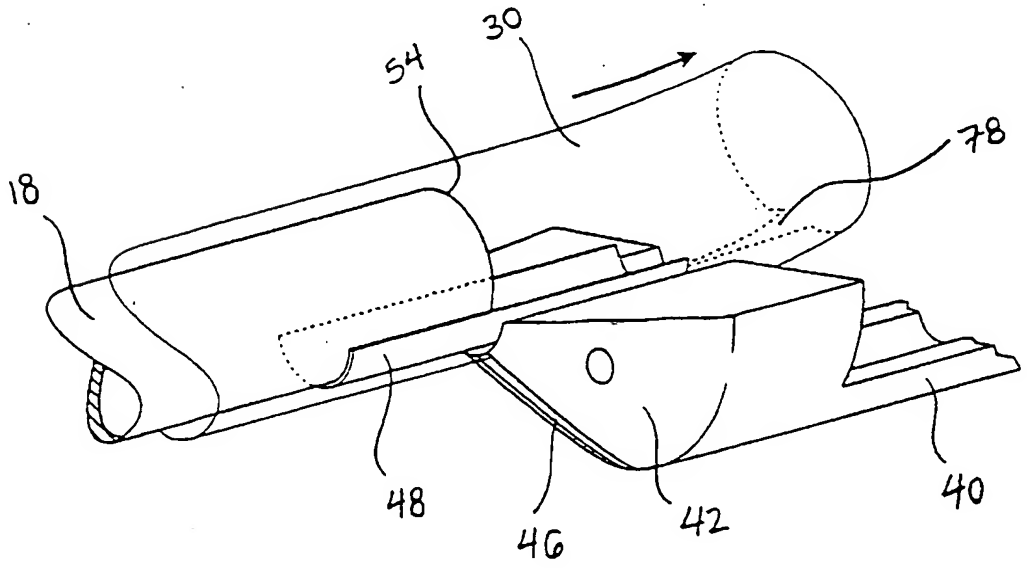


FIG. 6A

FIG. 6B



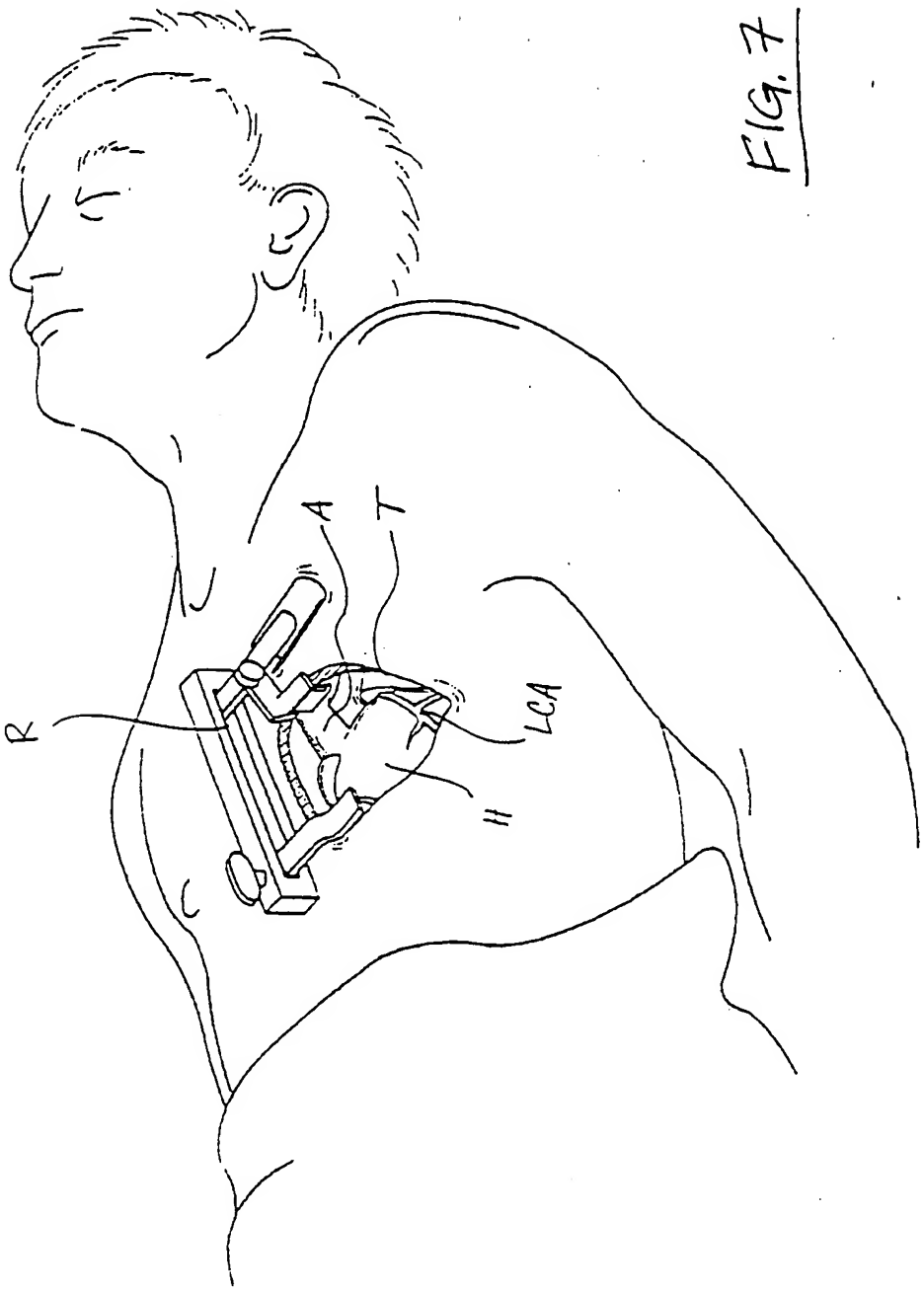


FIG. 7

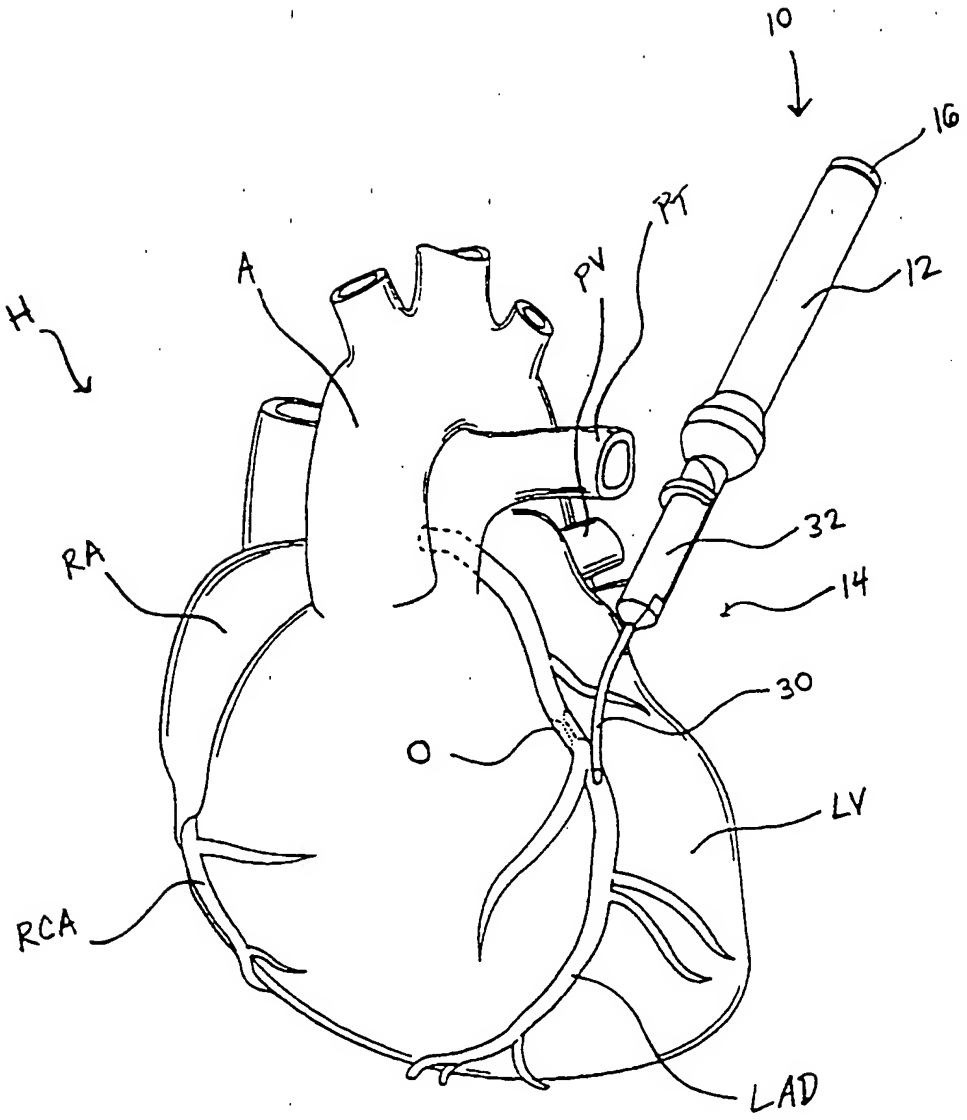


FIG. 8

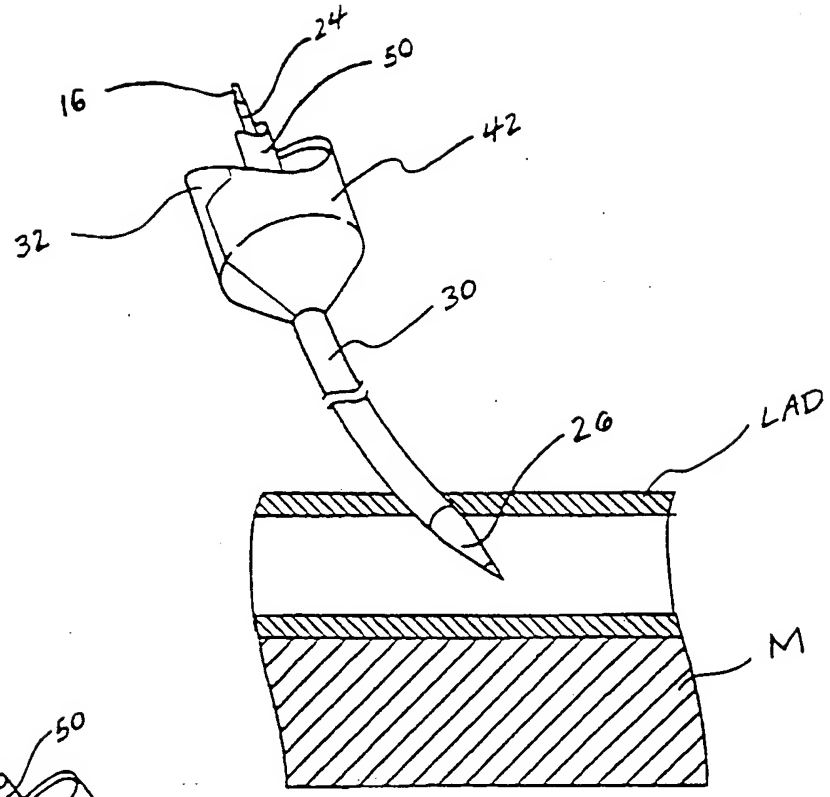


FIG. 9A

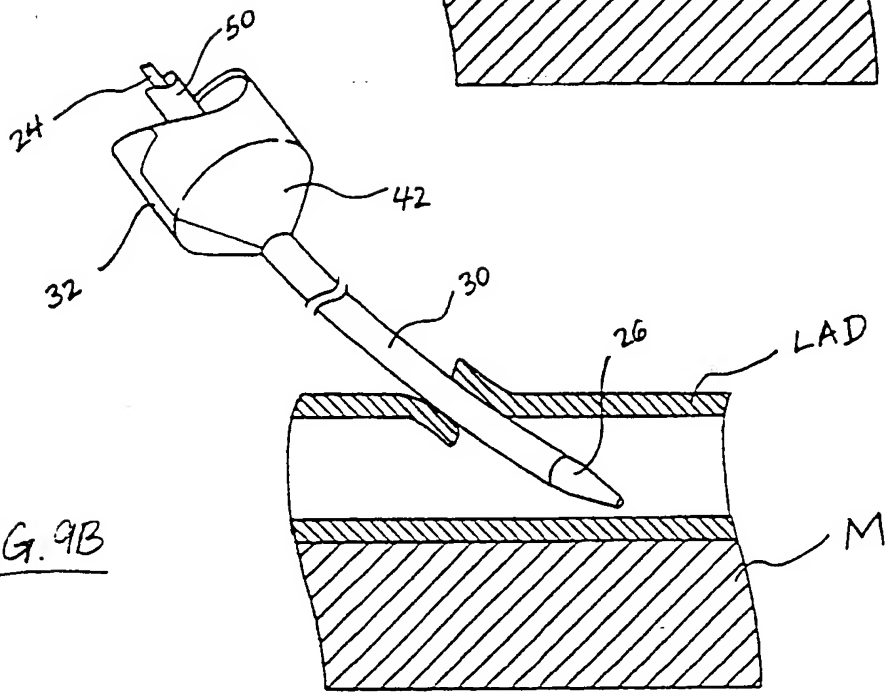


FIG. 9B

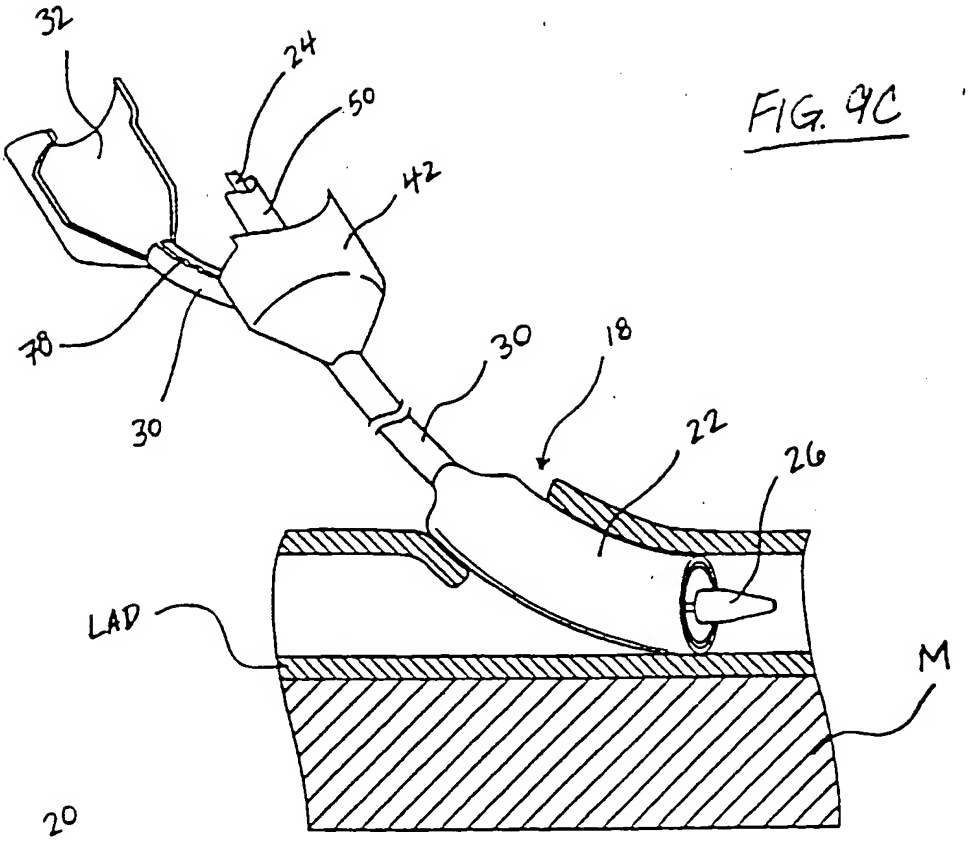


FIG. 9C

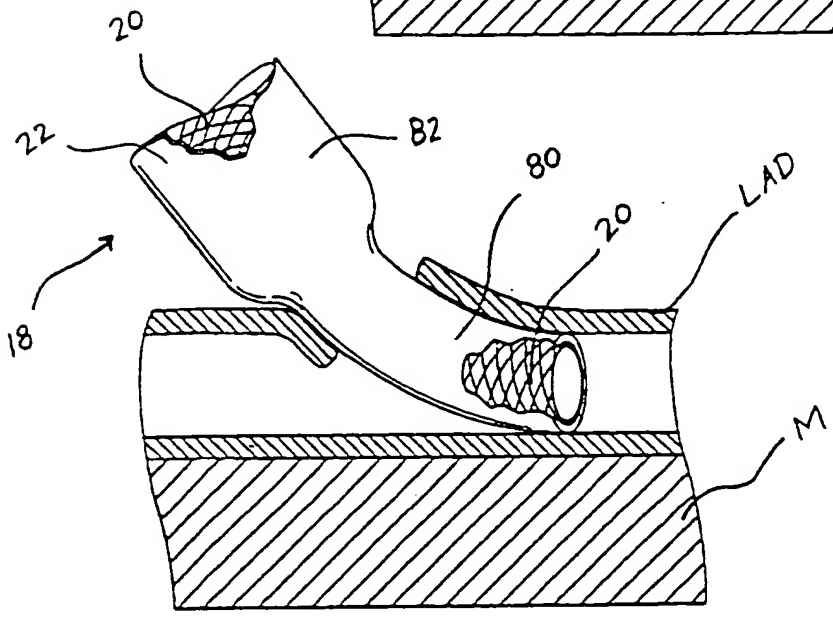


FIG. 9D

FIG. 10

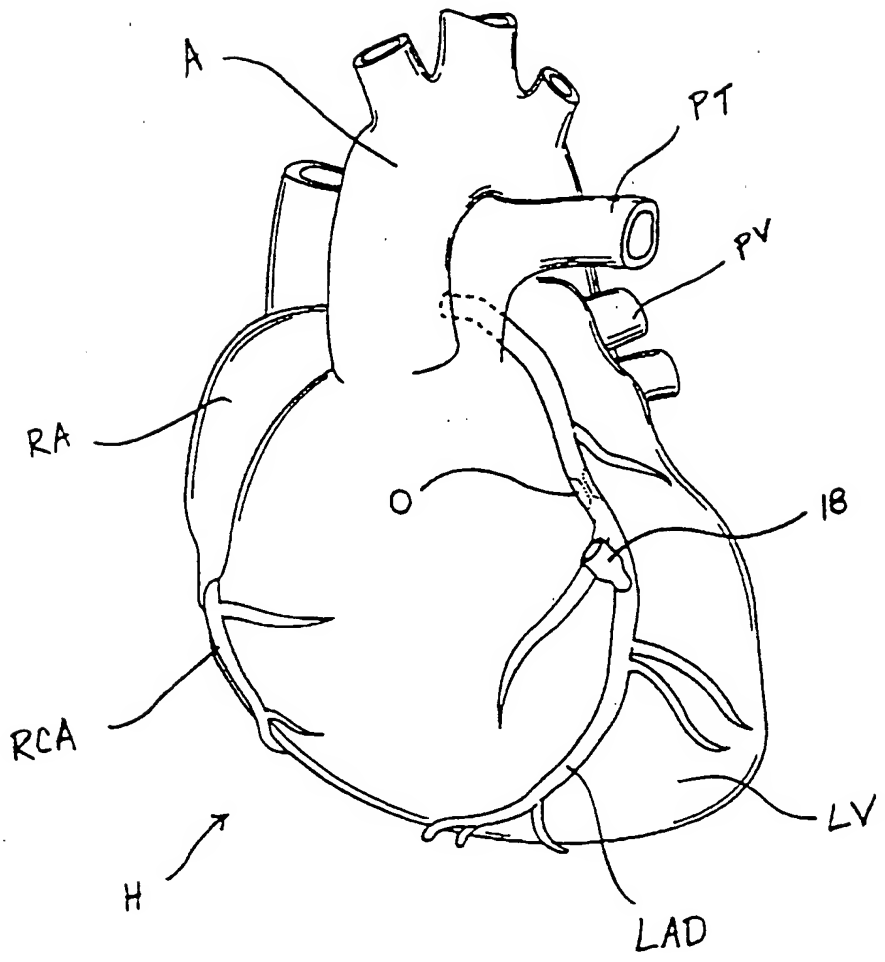


FIG. 10A

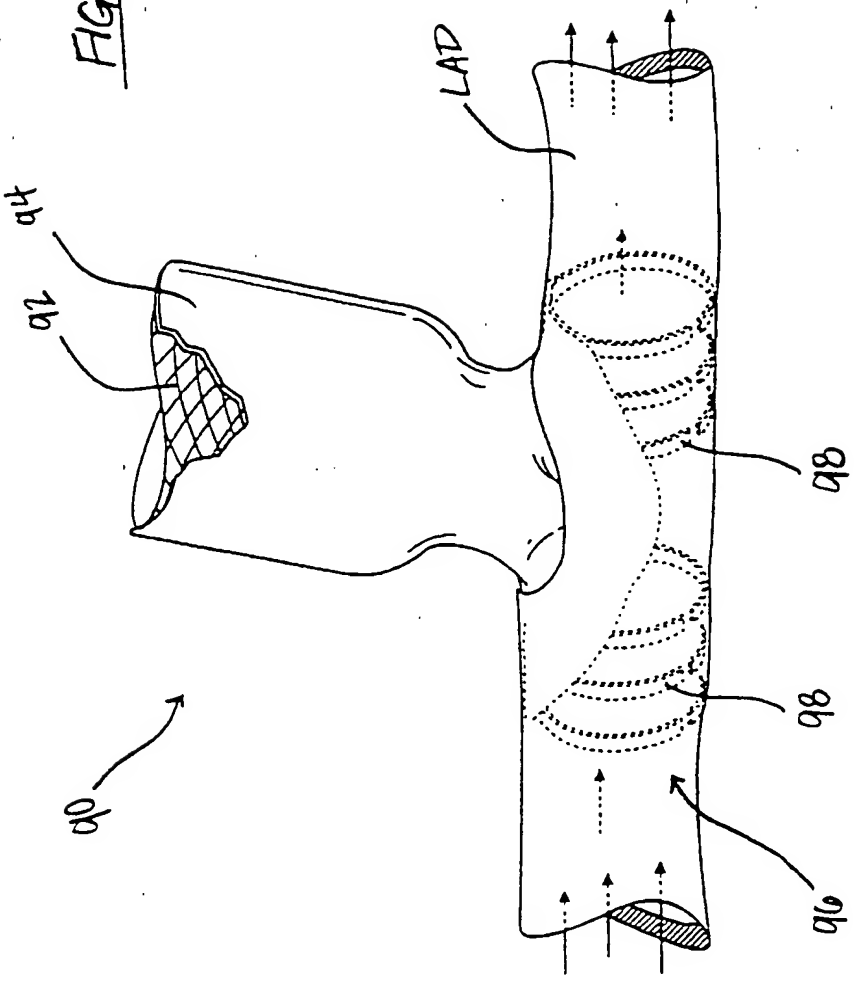


FIG. 11

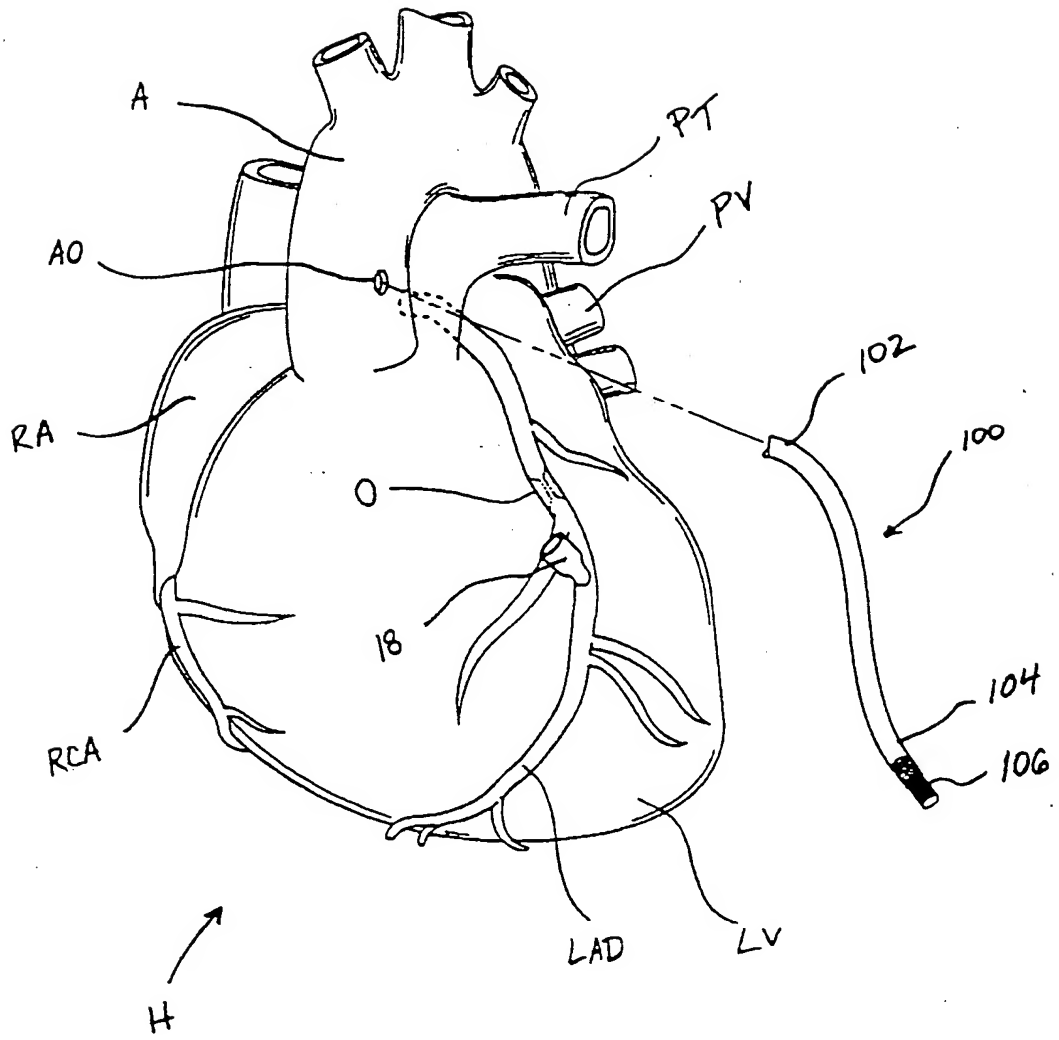


FIG. 12A

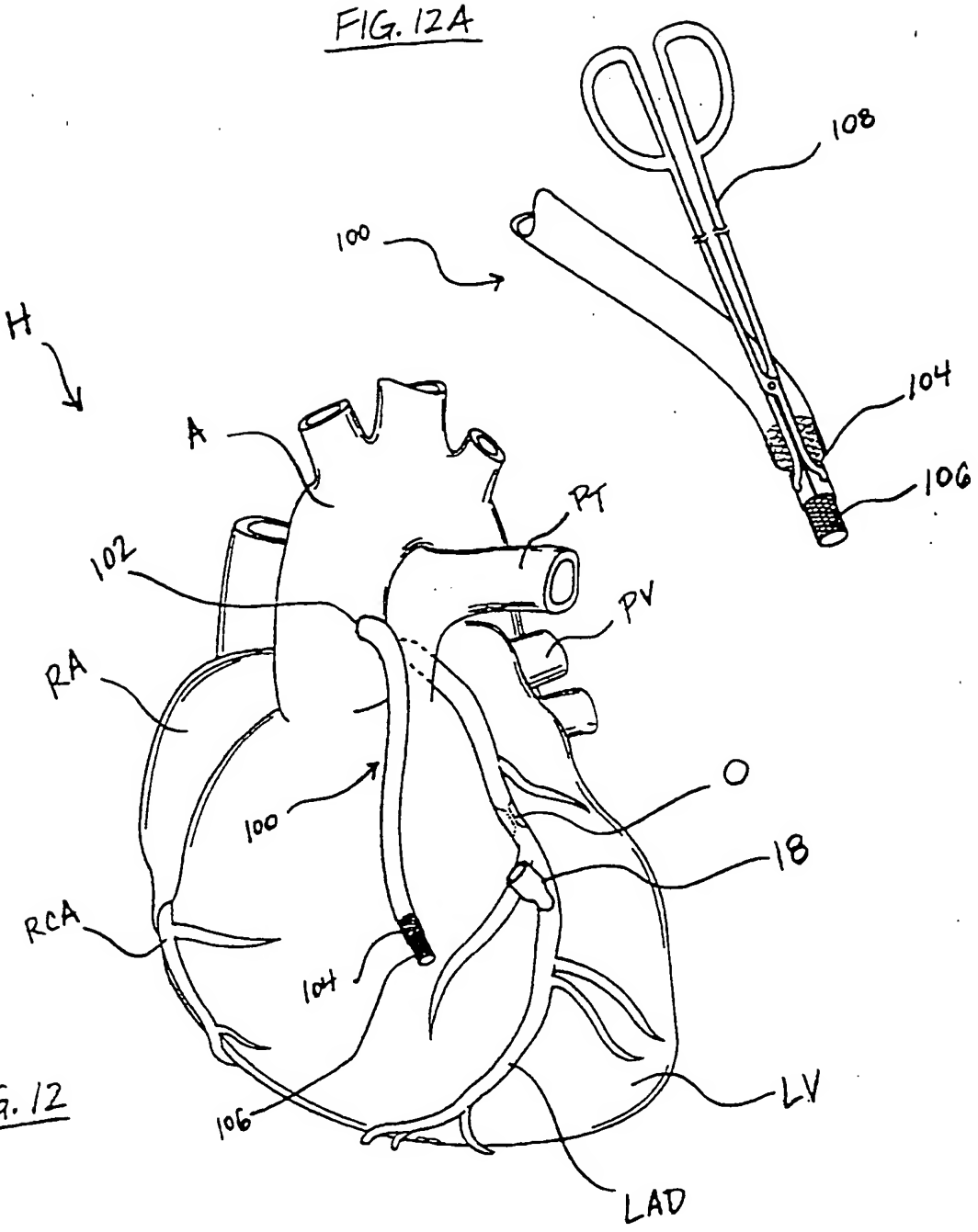


FIG. 12

FIG. 13

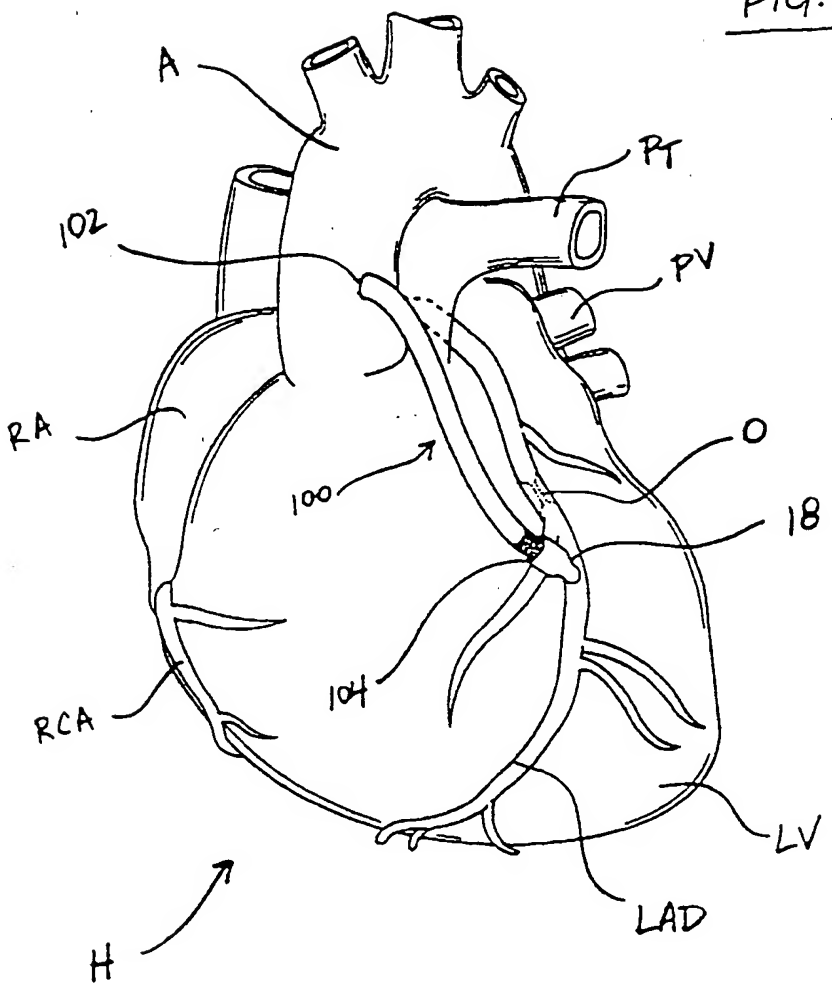
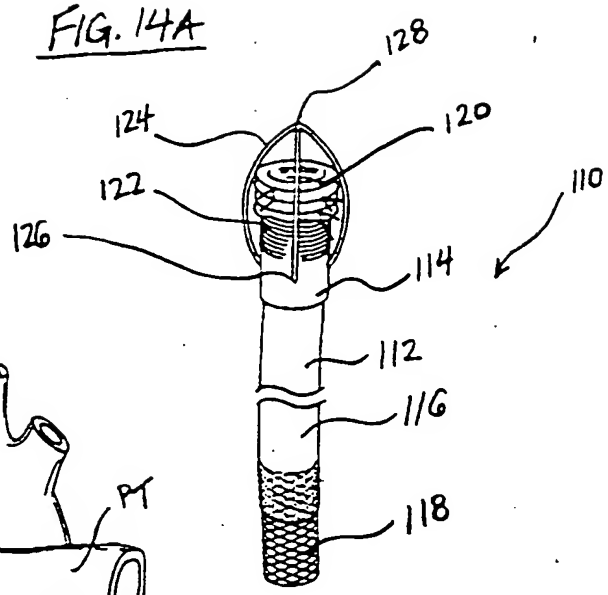


FIG. 14A



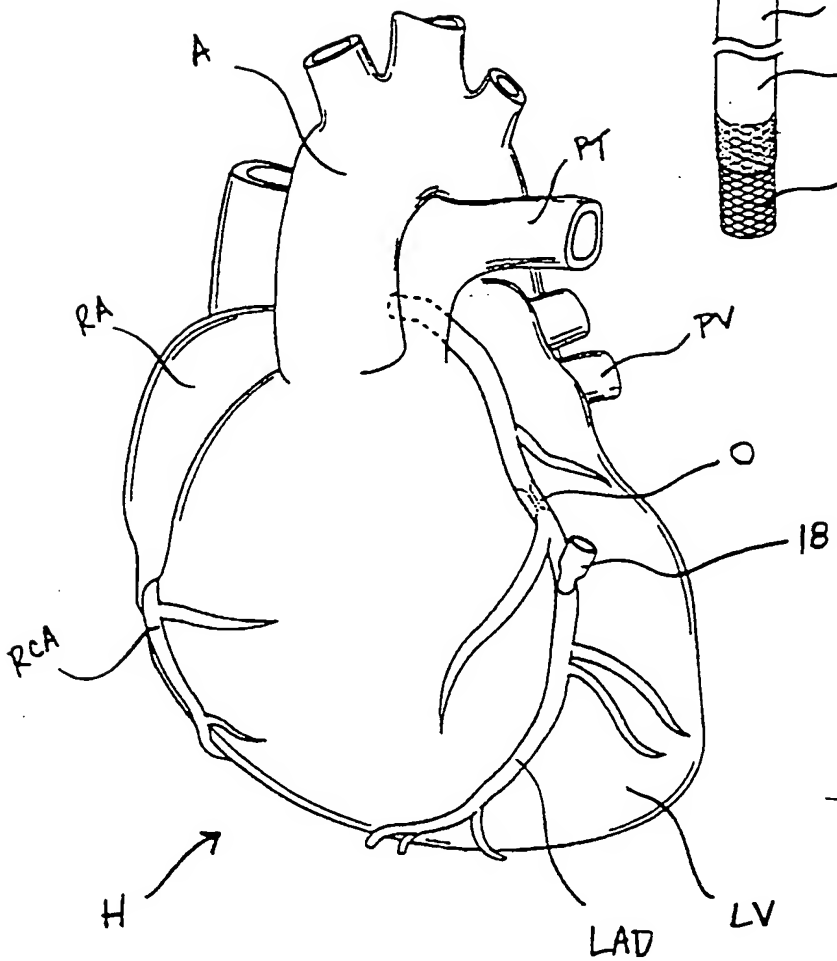


FIG. 14

FIG. 15A

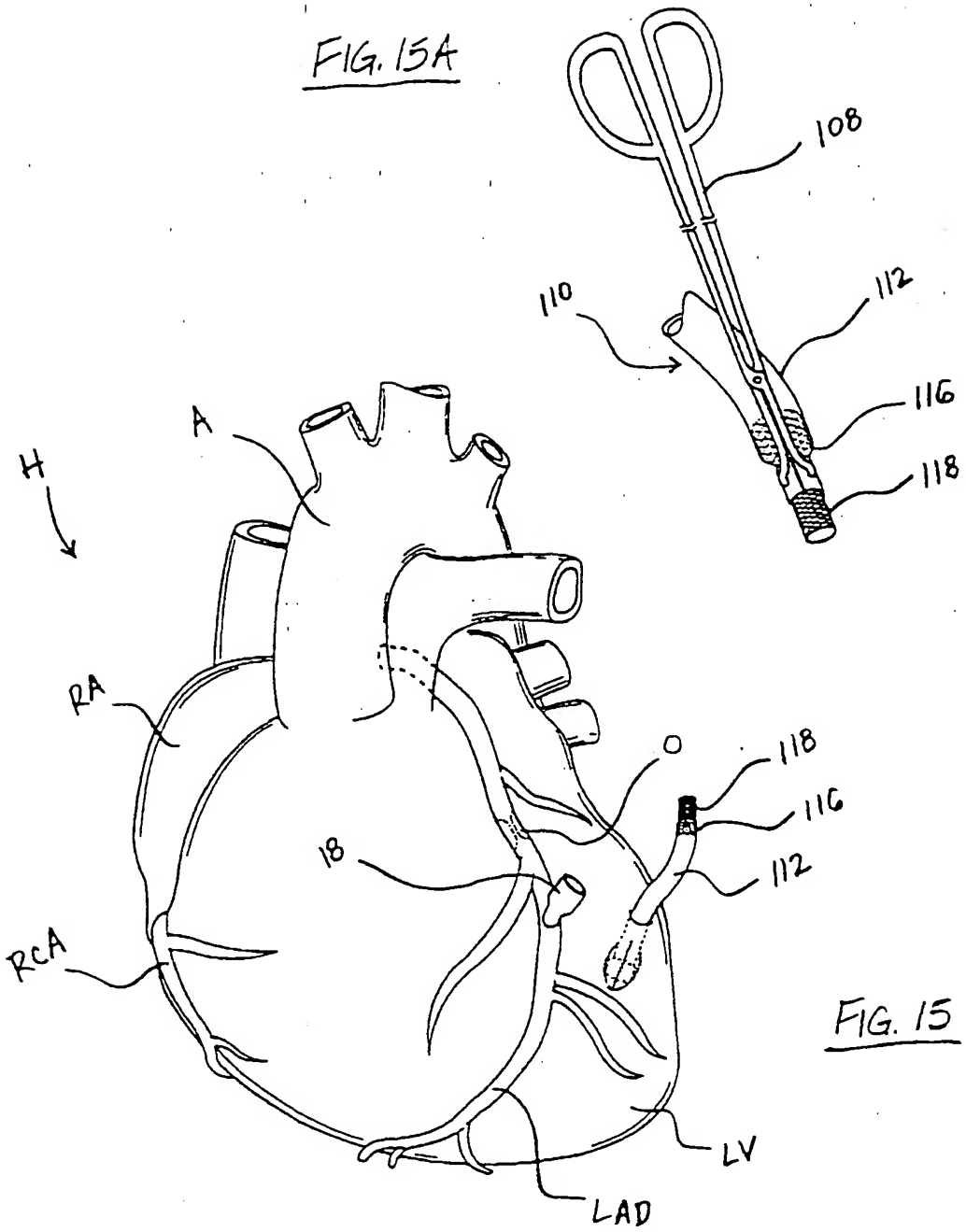


FIG. 15

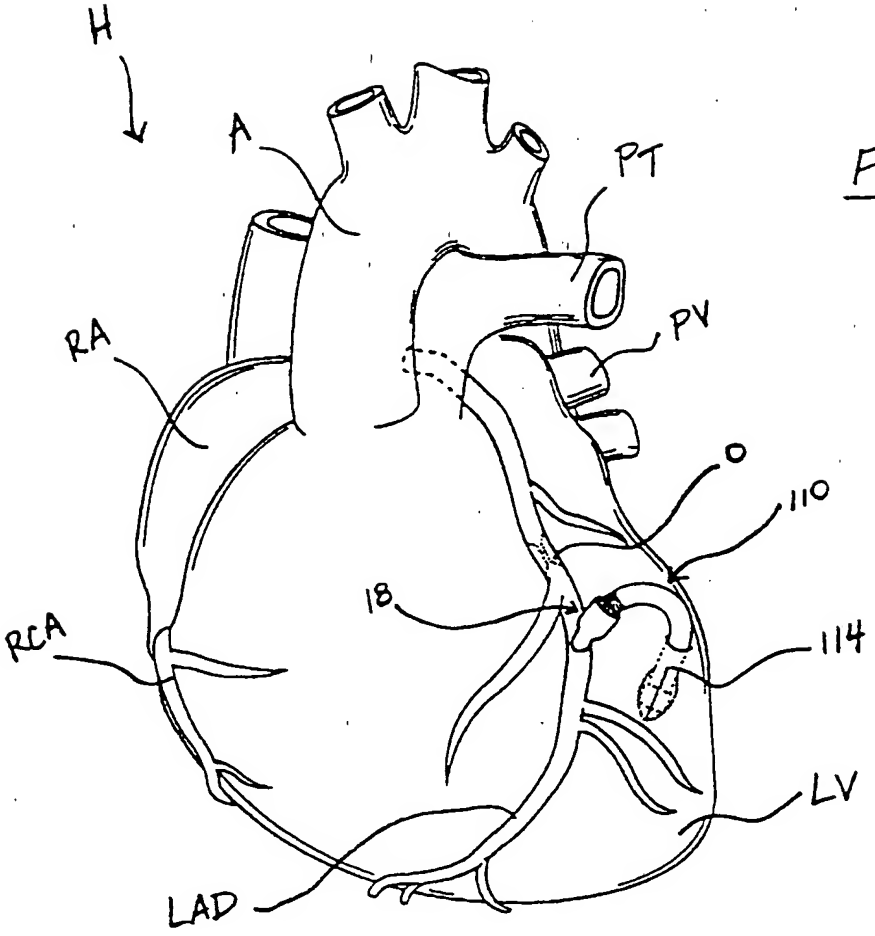


FIG. 16

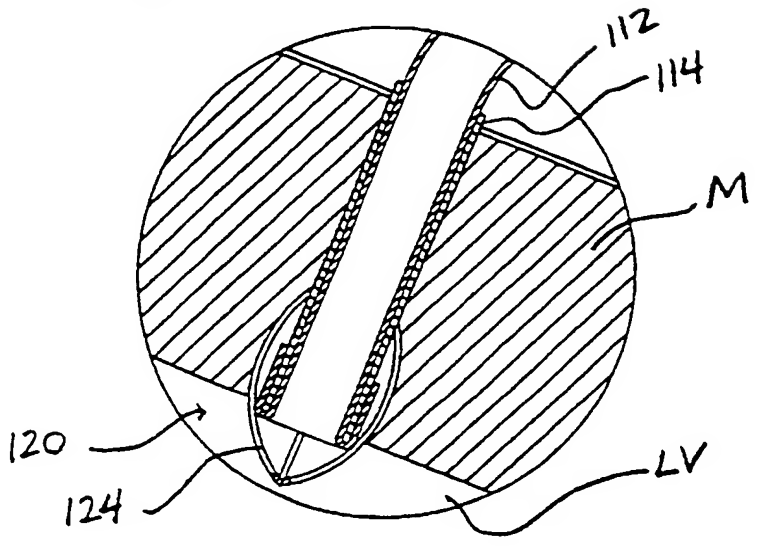


FIG. 16A

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US00/12073

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) :A61B 17/04
US CL :606/153, 154, 194, 198; 623/1, 1.13

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/153, 194, 198, 154; 623/1, 1.13

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,522,880 A (BARONE et al.) 04 June 1996, entire document.	1-39

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search 15 AUGUST 2000	Date of mailing of the international search report 30 AUG 2000
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer VIKKI TRINH Telephone No. (703) 308-8238

Form PCT/ISA/210 (second sheet) (July 1998)*